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Presidential Documents

Title 3—

The President

Proclamation 10707 of March 1, 2024

National Consumer Protection Week, 2024

By the President of the United States of America

A Proclamation

As my Administration continues to build an economy that works for everyone, we cannot let fraud, cybercrimes, or unfair business practices interrupt the progress we have made. During National Consumer Protection Week, we recommit to protecting the rights of consumers and spreading awareness about the resources people have to defend themselves from predatory acts.

Since I took office, we have made enormous progress in building an economy from the middle out and the bottom up. To date, we have created nearly 15 million jobs, driven stable economic growth, and brought down inflation by two-thirds from its peak. Still, I know we have more work to do to protect the progress we have made by defending American consumers from unfair business practices.

In my first year in office, I issued an Executive Order on Promoting Competition in the American Economy, which directs and encourages Federal agencies to find ways to address powerful corporations' use of their market dominance to inflate prices of consumer goods and services. These corporations are also decreasing the quality of goods and services, deterring innovation, and limiting job mobility. Since then, agencies across the Federal Government have taken decisive action to encourage competition and lower costs for American households.

The Department of Justice and the Federal Trade Commission (FTC) are cracking down on anticompetitive mergers, price fixing and price gouging, and other unfair practices that harm consumers. The Department of Agriculture has joined the effort to enforce antitrust and consumer protection laws in food and agriculture, which not only protect American families but farmers as well. At the same time, the FTC is working on a rule that would, if finalized as proposed, put an end to noncompete agreements, which restrict 30 million workers from switching jobs, even if they have opportunities that offer better pay and benefits. The FTC is also engaged in a rulemaking that proposes to require that companies make it as easy to cancel an online enrollment as it was to sign up so you are not left paying unwanted subscription fees because of a difficult cancellation process. The FTC is working with law enforcement to counter predatory student loan scams, mortgage scams, and identity theft.

My Administration is fighting to eliminate hidden junk fees that some banks, airlines, health care companies, and other organizations use to rip off their customers. Since 2021, 15 of the 20 largest banks have responded to my call to stop charging customers for bounced checks and reduce overdraft fees, saving Americans $5.5 billion annually in eliminated junk fees. The Consumer Financial Protection Bureau (CFPB) has proposed a rule that will slash credit card late fees from an average of $31 when I took office to a new cap of $8, which will save Americans more than $9 billion annually. The CFPB is also taking steps to cut the average overdraft fee by more than half, down from its typical amount of over $30, a move that would save $150 per year for the more than 20 million households that pay these fees. The CFPB has also banned banks and credit unions from charging fees for basic services, like checking an account balance

or retrieving old bank records. In addition, it has proposed a new rule that would make it easier for customers to switch banks, encouraging them to compete for customers based on the quality of their services.

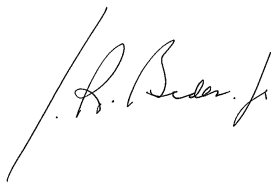
The Department of Labor proposed a new rule that would, if finalized as proposed, minimize junk fees in retirement products by requiring financial advisers to provide retirement advice in the best interest of the saver. The Department of Health and Human Services and the Department of the Treasury have proposed a rule that would protect Americans from getting ripped off by health plans offering junk insurance that discriminate based on preexisting conditions and trick consumers into buying insurance that provides little or no coverage when they need it most. Further, the Department of Transportation has challenged airlines to improve unfair business practices. Some airlines have already responded by eliminating fees that charge parents just to sit next to their child on a plane. Many have also begun guaranteeing free rebooking and reimbursement for hotels, meals, and ground transportation if a flight cancellation or delay is the airline's fault. Just last year, we saw the lowest rate of flight cancellations in a decade.

The FTC has enhanced its translation resources to make it easier for consumers to submit fraud reports and learn how to spot and avoid scams in languages other than English. Meanwhile, we are continuing to work with partners across the Government and in our communities to amplify and expand language access for consumers. Last year, the FTC proposed a rule that would ban hidden fees across the economy and require all companies to show consumers the all-in pricing of products upfront.

The American people should never be played like suckers. It is up to each of us to protect one another from harmful anticompetitive business practices. This National Consumer Protection Week, I encourage every American to visit consumer.ftc.gov to learn more about the resources available to defend the rights of consumers. I also encourage people to report cases of suspected fraud, issues with a consumer financial product, aggressive debt collection, inaccurate credit reporting, or unfair medical billing and other issues by visiting consumerfinance.gov/complaint online.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 3, 2024, through March 9, 2024, as National Consumer Protection Week. I call upon government officials, industry leaders, and advocates across the Nation to share information about consumer protection and provide our citizens with information about their rights as consumers.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



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Presidential Documents

Proclamation 10708 of March 1, 2024

Read Across America Day, 2024

By the President of the United States of America

A Proclamation

On Read Across America Day, we celebrate the power of literacy to expand our minds and our understanding of the world around us. We salute all the parents, educators, authors, librarians, and mentors who encourage our children to read, and we appreciate the literature that dares them to think big.

For so many children, their dreams begin with a book. Whether it is through the stories they listen to at bed time or a trip to the local library, books introduce children to new ideas, cultures, and perspectives. They feed the imagination and stoke the fires of innovation that help them understand our world as it is and pioneer ways to make it better. I know firsthand how reading can change lives: the First Lady, a lifelong book lover, pursued a career as an educator because she wanted to share the gift of reading with people who ''didn't know that joy.'' As a community college professor, she continues to share that gift and remains committed to supporting all the teachers who do the same for their students.

The First Lady and I recognize there is still more work to do to improve literacy across the country. For more than a decade, studies show that reading competency of American students has been on the decline—and the impact of the COVID–19 pandemic only made things worse. That is why, since day one of my Administration, we have been committed to supporting educators and improving literacy—from our youngest readers to adults.

To get our schools back open and running during the pandemic, my American Rescue Plan secured $130 billion, putting more teachers in our classrooms and more counselors in our schools. This funding is providing high-quality tutoring, expanding summer and after-school programming, and increasing student engagement. Over the past 3 years, school districts have added more than 610,000 educators and staff. Our National Partnership for Student Success is working to add another 250,000 caring adults in tutoring, mentoring, and other critical support roles. That equals hundreds of thousands of additional professionals who are giving students the support they deserve.

We also know that early education is a powerful stepping stone for academic success. Research shows that children who start school at 3 and 4 years old are more likely to graduate from high school and further their education. It is a big reason why I am working to ensure that every child in America has access to high-quality preschool.

We are also supporting adults in their efforts to become better readers through my Administration's Adult Education State Grants. These grants support adult literacy programs and provide the skills and resources needed to gain employment—from obtaining a secondary school diploma to transitioning to a postsecondary school.

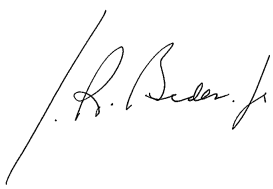
This Read Across America Day, we must also acknowledge a difficult truth—that our children are growing up in a country where some extremist politicians are banning books in grade schools and high schools. In America,

we do not ban books. Rather, we celebrate the full diversity of stories and perspectives—and their potential to expand our horizons.

Dr. Seuss once wrote, ''The more that you read, the more things you will know. The more that you learn, the more places you'll go.'' Today, may we celebrate the power that is unleashed by reading—discovering the comfort of words in times of sorrow, finding inspiration to fuel our imagination, or having a clear-eyed understanding of our past so we can forge a future of limitless possibilities.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 2, 2024, as Read Across America Day. I call upon children, families, educators, librarians, public officials, and all the people of the United States to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



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Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 982

[Doc. No. AMS–SC–23–0034]

Hazelnuts Grown in Oregon and Washington; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This final rule implements a recommendation from the Hazelnut Marketing Board (Board) to decrease the assessment rate established for the 2023–2024 marketing year and subsequent marketing years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: This rule is effective April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Virginia Tjemsland, Marketing Specialist, or Barry Broadbent, Acting Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2282, or Email: *Virginia.L.Tjemsland@usda.gov* or *Barry.Broadbent@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Agreement No. 115 and Order No. 982, both as amended (7 CFR part 982), regulating the handling of hazelnuts grown in Oregon and Washington. Part 982 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Board locally administers the Order and is composed of growers and handlers of hazelnuts operating within the area of production, and a public member.

The Agricultural Marketing Service (AMS) is issuing this final rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 supplements and reaffirms Executive Orders 12866 and 13563 and directs agencies to conduct proactive outreach to engage interested and affected parties through a variety of means, such as through field offices, and alternative platforms and media. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866, 13563, and 14094 review.

This final rule has been reviewed under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, hazelnut handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable hazelnuts for the 2023–2024 marketing year, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

Section 982.61 provides authority for the Board, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Members are familiar with the Board's needs and with the costs of goods and services in their local area and are, thus, in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2017–2018 marketing year and subsequent marketing years, the Board recommended, and AMS approved, an assessment rate of $12 per ton (equivalent to $0.006 per pound) of hazelnuts. That rate continues in effect from marketing year to marketing year until modified, suspended, or terminated by AMS upon recommendation and information submitted by the Board or other information available to AMS. This final rule will decrease the assessment rate from $0.006 per pound to $0.005 per pound for the 2023–2024 marketing year and subsequent marketing years.

The Board met on June 29, 2023, and recommended 2023–2024 marketing year expenditures of $1,815,000 and an assessment rate of $10 per ton (the equivalent of $0.005 per pound) of hazelnuts handled for the 2023–2024

marketing year and subsequent marketing years. In comparison, last year's budgeted expenditures were $2,378,550. The assessment rate of $0.005 per pound is $0.001 lower than the rate currently in effect. The Board recommended decreasing the assessment rate to better align assessment revenue with budgeted expenses and to reduce the financial burden on the industry in a period of low commodity prices. The Board projects handler receipts of 85,000 tons (170 million pounds) of hazelnuts for the 2023–2024 marketing year, which is 10,000 tons (20 million pounds) more than was projected for the 2022–2023 marketing year.

The expenditures totaling $1,815,000 recommended by the Board for the 2023–2024 marketing year include $670,000 for promotional activities, $300,000 for contingency/undesignated, $100,000 for marketing research, $100,000 for research endowment, $378,000 for administrative activities, and $267,000 for miscellaneous expenses. By comparison, budgeted expenditures for the 2022–2023 marketing year for promotional activities, contingency, marketing research, research endowment, administrative activities, and miscellaneous expenses were $1,251,200, $200,000, $150,000, $100,000, $347,350, and $330,000, respectively. The Board's 2023–2024 marketing year budget was reduced to account for generally lower commodity prices and decreased industry revenue.

The expected 170 million pounds of assessable hazelnuts from the 2023 crop will generate $850,000 in assessment revenue at the assessment rate established herein (170 million pounds multiplied by $0.005 assessment rate). The remaining $965,000 needed to cover budgeted expenditures will come from new grant funds and reserve funds carried over from previous marketing years. The Board anticipates $495,000 in Federal grants administered by USDA's Foreign Agricultural Service.[1] The remaining $470,000 necessary to cover budgeted expenditures will come from its monetary reserve. The decreased assessment rate should be appropriate to ensure that the Board has sufficient revenue, along with grants awarded and reserve funds, to fully fund its 2023–2024 marketing year budgeted expenditures and still maintain a level of reserve funds that the Board believes is appropriate.

The Board derived the recommended assessment rate by considering anticipated expenses, an estimated 2023 crop volume of 170 million pounds of assessable hazelnuts, grants that have been awarded, and the amount of funds available in the authorized reserve. Income derived from handler assessments ($850,000), and funds from other sources ($965,000), is expected to be adequate to cover budgeted expenses ($1,815,000).

The assessment rate established herein will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Board or other available information.

Although this assessment rate will be in effect for an indefinite period, the Board will continue to meet prior to or during each marketing year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Board meetings are available from the Board or AMS. Board meetings are open to the public and interested persons may express their views at these meetings. AMS would evaluate Board recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Board's 2023–2024 marketing year budget, and those for subsequent marketing years, will be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this final rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of typically small entities acting on their own behalf.

There are approximately 1,103 producers of hazelnuts in the production area and 14 handlers subject to regulation under the Order. At the time this analysis was prepared, small agricultural producers of hazelnuts were defined by the Small Business Administration (SBA) as those having annual receipts equal to or less than $3,750,000 (North American Industry Classification System code 111335), and small agricultural service firms were defined as those whose annual receipts are equal to or less than $34,000,000 (North American Industry Classification System code 115114) (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the average producer price received for hazelnuts sold in Oregon specifically in 2022 was $1,300 per ton. Total production of hazelnuts for the 2022 season was reported by the NASS to be 68,000 tons. Using the average price and production data from the 2022 crop year, the most recent year for which there is NASS data available, the total 2022 crop value of hazelnuts could be estimated to be $88,400,000 (68,000 tons times $1,300 per ton). Dividing the crop value by the estimated number of producers (1,103) yields estimated average receipts per hazelnut producer of $80,145, which is well below the SBA threshold for small producers.

In addition, according to AMS Market News data, the reported average 2021–2022 marketing year shipping point price for hazelnuts was $126.82 per 50-pound container, or $2.54 per pound ($126.82 per 50-pound container divided by 50 pounds). Multiplying the 2022 hazelnut production of 136,000,000 pounds (68,000 tons) by the estimated average price per pound of $2.54 equals $345,440,000 of estimated handler receipts. Dividing this figure by the 14 regulated handlers yields estimated average annual handler receipts of approximately $24,674,286 ($345,440,000 divided by 14 handlers), which is below the SBA threshold for small agricultural service firms. Therefore, using the above data, most of the producers and handlers of hazelnuts may be classified as small entities.

This rule will decrease the assessment rate collected from handlers for the 2023–2024 marketing year and subsequent marketing years from $0.006 to $0.005 per pound of assessable hazelnuts. The Board unanimously recommended 2023–2024 marketing year expenditures of $1,815,000 and an assessment rate of $10 per ton ($0.005 per pound) of assessable hazelnuts. The assessment rate of $0.005 per pound is $.001 lower than the current rate. The Board expects the industry to handle 85,000 tons (170 million pounds) of assessable hazelnuts during the 2023–2024 marketing year.

Thus, at the $0.005 per pound rate, the Board anticipates $850,000 in assessment income (170 million pounds multiplied by $0.005 per pound). The Board also expects to use grant funds

[1] Specifically, $110,000 in Agricultural Trade Promotion program funds, $300,000 in Market Access Program funds, and $85,000 in Technical Assistance for Specialty Crop program funds.

and the Board's monetary reserve to cover the remaining $965,000 of expenses. Income derived from handler assessments, along with grants and reserve funds, should be adequate to meet budgeted expenditures for the 2023–2024 marketing year.

The major expenditures recommended by the Board for the 2023–2024 marketing year include $670,000 for promotional activities, $300,000 for contingency/undesignated, $100,000 for marketing research, $100,000 for research endowment, $378,000 for administrative activities, and $267,000 for miscellaneous expenses. Budgeted expenditures for the 2022–2023 marketing year were $1,251,200 for promotional activities, $200,000 for contingency/undesignated, $150,000 for marketing research, $100,000 for research endowment, $347,350 for administrative activities, and $330,000 for miscellaneous, respectively.

The Board's 2023–2024 marketing year budget was reduced $563,550 from the prior year's budget to account for generally lower commodity prices and decreased industry revenue. In addition, the Board recommended decreasing the assessment rate to reduce the financial burden on the handlers and growers during the current environment of depressed prices. In recent years, the Board has utilized reserve funds to partially fund its budgeted expenditures. The Board's 2023–2024 marketing year budget again utilizes funds from the financial reserve to subsidize expenditures, but at a lower amount than in previous years. With this action, the Board's reserve balance will be maintained at a level that the Board believes is appropriate and is compliant with the provisions of the Order.

Prior to arriving at the budget and assessment rate, the Board discussed various alternatives, including maintaining the current assessment rate of $0.006 per pound and reducing the assessment rate to $0.0055 per pound ($11 per ton). However, the Board determined that the recommended assessment rate will be able to reduce the financial burden on the industry and still fund most of the Board's budgeted expenses without drawing down reserves at an unsustainable rate. The assessment rate of $0.005 per pound of hazelnuts was derived by considering anticipated expenses, the projected volume of assessable hazelnuts, the projected monetary balance held in reserve, and additional pertinent factors.

A review of NASS information indicates that the average producer price for the 2022 crop year was $0.65 per pound ($1,300 per ton). Further, NASS reported the quantity of hazelnuts harvested in the 2022 crop year was 136 million pounds (68,000 tons), which yields estimated total producer revenue for 2022 of $88,400,000 ($0.65 per pound multiplied by 136 million pounds). Therefore, utilizing the assessment rate of $0.005 per pound, the estimated assessment revenue as a percentage of total producer revenue will be approximately 0.77 percent ($0.005 per pound multiplied by 136 million pounds divided by $88,400,000 and multiplied by 100).

This action will decrease the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, these costs are expected to be offset by the benefits derived by the operation of the Order.

The Board's meetings are widely publicized throughout the production area. The hazelnut industry and all interested persons are invited to attend the meetings and participate in Board deliberations on all issues. Like all Board meetings, the June 29, 2023, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements will be necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This final rule will not impose any additional reporting or recordkeeping requirements on either small or large hazelnut handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rulemaking concerning this action was published in the **Federal Register** on November 9, 2023 (88 FR 77233). A copy of the proposed rulemaking was made available through the internet by AMS via *https://www.regulations.gov.* A 30-day comment period ending on December 11, 2023, was provided for interested persons to respond to the proposal. AMS received one comment in support of the assessment change. Accordingly, no changes have been made to the rulemaking as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rulesregulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Board and other available information, AMS has determined that this rule tends to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 982

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 982 as follows:

PART 982—HAZELNUTS GROWN IN OREGON AND WASHINGTON

■ 1. The authority citation for 7 CFR part 982 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Revise § 982.340 to read as follows:

§ 982.340 Assessment rate.

On and after July 1, 2023, an assessment rate of $0.005 per pound is established for Oregon and Washington hazelnuts.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–04730 Filed 3–5–24; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 24

[CBP Dec. 24–05; Docket No. USCBP–2018–0033]

RIN 1515–AE39

Refund of Alcohol Excise Tax

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with no changes, interim amendments to the U.S. Customs and Border Protection (CBP) regulations that were published in the **Federal Register** on December 30, 2022, as CBP Decision 22–26. Pursuant to these changes, the responsibility for administering refunds, reduced tax rates, and tax credits on imported alcohol moved from CBP to the U.S. Department of the Treasury, on January 1, 2023.

DATES: This rule is effective as of March 6, 2024.

FOR FURTHER INFORMATION CONTACT: Kellee Gross, Branch Chief, Trade Processes Branch, Office of Trade, 202–815–1699, *kellee.m.gross@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Sections 13801–13808 of the Tax Cuts and Jobs Act of 2017 (Pub. L. 115–97), signed December 22, 2017, commonly referred to as the Craft Beverage Modernization Act (CBMA), amended the Internal Revenue Code for two calendar years with respect to the tax treatment of imported alcohol, including beer, wine, and distilled spirits. The CBMA authorized reduced tax rates and tax credits for imported alcohol and permitted the refund of taxes paid prior to assigning a reduced tax rate or tax credit. On August 16, 2018, U.S. Customs and Border Protection (CBP) published an interim final rule, CBP Decision (CBP Dec.) 18–09, in the **Federal Register** (83 FR 40675), updating the language of title 19 of the Code of Federal Regulations (CFR) to implement the CBMA and make other technical changes to 19 CFR part 24.

On December 19, 2019, the Further Consolidated Appropriations Act was signed, which extended the relevant provisions of the CBMA through calendar year 2020. *See* Public Law 116–94. On December 27, 2020, the Taxpayer Certainty and Disaster Tax Relief Act of 2020 (Tax Relief Act) was enacted. *See* Public Law 116–260, Division EE, sections 106–110. The Tax Relief Act amended and made permanent the CBMA, and directed the Secretary of the Treasury to implement and administer amended provisions concerning imported alcohol, in coordination with CBP. This authority was subsequently delegated to the Alcohol and Tobacco Tax and Trade Bureau (TTB). The relevant provisions of the Tax Relief Act became effective on January 1, 2023.

On December 30, 2022, CBP published an interim final rule, CBP Dec. 22–26, in the **Federal Register** (87 FR 80442) to update the regulations issued in CBP Dec. 18–09, to reflect the transfer of authority for administration of the CBMA import refund program to TTB, and to direct the public to the relevant TTB regulations regarding refunds administered by TTB, in 27 CFR parts 27 and 70. Specifically, the interim final rule amended section 24.36 of title 19 of the Code of Federal Regulations (19 CFR 24.36). CBP Dec. 22–26 provided for the submission of comments from December 30, 2022, to March 2, 2023. No comments were received.

II. Conclusion

CBP is adopting as final the interim rule, CBP Dec. 22–26, published in the **Federal Register** (87 FR 80442) on December 30, 2022, without changes.

III. Statutory and Regulatory Requirements

A. Executive Orders 13563, 12866, and 14094

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, the Office of Management and Budget (OMB) has not reviewed this regulation.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this final rule, CBP is not required to prepare a regulatory flexibility analysis for this final rule.

C. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule, because this final rule does not trigger any new or revised recordkeeping or reporting.

IV. Signing Authority

This final rule is being issued by CBP in accordance with section 0.1(a)(1) of the CBP regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or the Secretary's delegate) to approve regulations related to certain customs revenue functions. The Senior Official Performing the Duties of the Commissioner Troy A. Miller, having reviewed and approved this document, has delegated the authority to electronically sign the document to the Director (or Acting Director, if applicable) of the Regulations and Disclosure Law Division of CBP, for purposes of publication in the **Federal Register**.

Amendments to the Regulations

List of Subjects in 19 CFR Part 24

Accounting, Claims, Harbors, Reporting and recordkeeping requirements, Taxes.

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

■ Accordingly, the interim final rule amending part 24 of title 19 of the Code of Federal Regulations (19 CFR part 24), which was published in the **Federal Register** at 87 FR 80442 on December

30, 2022 (CBP Dec. 22–26), is adopted as final, without change.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury for Tax Policy.

[FR Doc. 2024–04711 Filed 3–5–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2024–N–0826]

Advisory Committee; Genetic Metabolic Diseases Advisory Committee; Addition to List of Standing Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the standing advisory committee regulations to add the establishment of the Genetic Metabolic Diseases Advisory Committee (GeMDAC or the Committee) to the list of standing committees.

DATES: This rule is effective March 6, 2024.

FOR FURTHER INFORMATION CONTACT: Moon Choi, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993, 301–796–2894, *GeMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established on December 12, 2023, and notice of establishment was published in the **Federal Register** on December 13, 2023 (88 FR 86344).

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug and biologic products for use in the treatment of genetic metabolic diseases and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

The Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of medical genetics, manifestations of inborn errors of metabolism, small population trial design, translational science, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee will serve either as special government employees or non-voting representatives. Federal members will serve as regular government employees or ex 1652fficious. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Committee name and function have been established with the establishment of the Committee charter. The change became effective December 12, 2023. Therefore, the Agency is amending § 14.100 (21 CFR 14.100) to add the Committee name and function to its current list as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(4)(B) and (d) and 21 CFR 10.40(d) and ©, the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule.

Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule is merely codifying the addition of the name and function of the GeMDAC to the list of standing FDA advisory committees. The establishment of the Committee is already effective, and the name and function that will be added to § 14.100 reflect the Committee charter. The Agency is amending § 14.100(c)(18) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. 1001 *et seq.;* 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264, 284m, 284m–1; Pub. L. 107–109, 115 Stat. 1419.

■ 2. Section 14.100 is amended by adding paragraph (c)(18) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(18) *Genetic Metabolic Diseases Advisory Committee.*

(i) Date Established: December 12, 2023.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug and biologic products for use in the treatment of genetic metabolic diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

* * * * *

Dated: March 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04751 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Great Lakes St. Lawrence Seaway Development Corporation

33 CFR Part 401

RIN 2135–AA55

Seaway Regulations and Rules: Periodic Update, Various Categories

AGENCY: Great Lakes St. Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Great Lakes St. Lawrence Seaway Development Corporation (GLS) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the GLS is amending the joint regulations by updating the regulations and rules in various categories. These changes are to clarify existing requirements in the regulations.

DATES: This rule is effective on March 22, 2024.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *https://*

www.Regulations.gov; or in person at the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Carrie Mann Lavigne, Chief Counsel, Great Lakes St. Lawrence Seaway Development Corporation, 180 Andrews Street, Massena, New York 13662; (315) 764–3200.

SUPPLEMENTARY INFORMATION: The Great Lakes St. Lawrence Seaway Development Corporation (GLS) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the GLS is amending the joint regulations by updating the Regulations and Rules in various categories. The changes update the following sections of the Regulations and Rules: Condition of Vessels, Seaway Navigation, Radio Communications, and Information and Reports. These changes are to clarify existing requirements in the regulations.

Regulatory Notices: Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *https://www.Regulations.gov.*

The joint regulations will become effective in Canada on March 22, 2024. For consistency, because these are joint regulations under international agreement, and to avoid confusion among users of the Seaway, the GLS finds that there is good cause to make the U.S. version of the amendments effective on the same date.

Regulatory Evaluation

This regulation involves a foreign affairs function of the United States and therefore, Executive Order 12866 does not apply and evaluation under the Department of Transportation's Regulatory Policies and Procedures is not required.

Regulatory Flexibility Act Determination

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. The St. Lawrence Seaway Regulations and Rules primarily relate to commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

Environmental Impact

This regulation does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, *et seq.*) because it is not a major Federal action significantly affecting the quality of the human environment.

Federalism

The Corporation has analyzed this rule under the principles and criteria in Executive Order 13132, dated August 4, 1999, and has determined that this proposal does not have sufficient federalism implications to warrant a Federalism Assessment.

Unfunded Mandates

The Corporation has analyzed this rule under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48) and determined that it does not impose unfunded mandates on State, local, and tribal governments and the private sector requiring a written statement of economic and regulatory alternatives.

Paperwork Reduction Act

This regulation has been analyzed under the Paperwork Reduction Act of 1995 and does not contain new or modified information collection requirements subject to the Office of Management and Budget review.

List of Subjects in 33 CFR Part 401

Hazardous materials transportation, Navigation (water), Penalties, Radio, Reporting and recordkeeping requirements, Vessels, Waterways.

Accordingly, the Great Lakes St. Lawrence Seaway Development Corporation is amending 33 CFR part 401 as follows:

PART 401—SEAWAY REGULATIONS AND RULES

Subpart A—Regulations

■ 1. The authority citation for part 401 continues to read as follows:

Authority: 33 U.S.C. 983(a) and 984(a)(4), as amended; 49 CFR 1.101, unless otherwise noted.

■ 2. Revise § 401.8 to read as follows:

§ 401.8 Landing booms.

(a) Vessels of more than 50 m in overall length and a freeboard of 2m or more shall either be equipped with landing booms or make their own provisions for tie-up at the approach walls.

(b) For vessels with landing booms:

(1) Vessel must be equipped with an adequate landing boom on each side;

(2) Landing booms must be in compliance with applicable regulations;

(3) Vessel's crews shall be adequately trained in the use of landing booms for the purpose of landing crew ashore.

(4) Vessel must have onboard for inspection the following documents:

(i) A copy of the test certificates for each of the landing booms from either a classification society or a third party, dated within 5 years;

(ii) Documents to demonstrate appropriate training;

(iii) Documented tests and maintenance records of landing boom equipment.

(c) At the U.S. Locks, vessels not equipped with or not using landing booms may be tied up at the approach walls based on Lock personnel availability.

(d) At the Canadian Locks, vessels not equipped with or not using landing booms should make alternate arrangements for tie-up at approach walls prior to commencing transit of the Seaway. Example: ship contract in place with a 3rd party service provider where ship is responsible for contacting provider.

(1) Vessels that do not have a tie-up strategy in place for the lock approach walls may be delayed and/or put to anchor until such time that the traffic pattern can accommodate their transit.

(2) [Reserved]

■ 3. Amend § 401.9 by adding new paragraphs (a)(1) and (a)(2) to read as follows:

§ 401.9 Radio telephone and navigation equipment.

(a) * * *

(1) All communications shall be on the applicable VHF frequency. The use of personal electronic devices for communication between vessels or with traffic control should be limited to necessity.

(2) Please note that communications into the Traffic Control Center may be recorded for quality assurance and training purposes.

* * * * *

■ 4. Amend § 401.19 by revising paragraph (a) and paragraph (b)(2) to read as follows:

§ 401.19 Disposal and Discharge Systems.

(a) Every vessel not equipped with containers for ordure shall be equipped with a sewage disposal system enabling compliance with the Vessel Pollution and Dangerous Chemicals regulations (Canada), the U.S. Clean Water Act, and the U.S. Rivers and Harbors Act of 1899, and amendments thereto.

(b) * * *

(2) Retained on board in covered, leak-proof containers, until such time as it can be disposed of in accordance with the provisions of the Vessel Pollution and Dangerous Chemicals regulations (Canada), the U.S. Clean Water Act and the U.S. Rivers and Harbors Act of 1899, and amendments thereto.

* * * * *

■ 5. Amend § 401.20 by revising paragraph (b)(4) to read as follows:

§ 401.20 Automatic Identification System.

* * * * *

(b) * * *

(4) International Maritime Organization (IMO) Guidelines for Installation of Shipborne Automatic Identification System (AIS), NAV 48/18, 6 January 2003, as amended, and, for ocean vessels only, with a pilot plug, as specified in Section 3.2 of those Guidelines, installed close to the primary conning position in the navigation bridge and a power source accessible for the pilot's laptop computer; and

* * * * *

■ 6. Amend § 401.29 by revising paragraphs (b) and (c) to read as follows:

§ 401.29 Maximum draft.

* * * * *

(b) The draught of a vessel shall meet minimum draft requirements as defined at inspection on the Enhanced Ship Inspection form and not, in any case, exceed 79.2 dm or the maximum permissible draught designated in a Seaway Notice by the Manager and the Corporation for the part of the Seaway in which a vessel is passing.

(c) Any vessel will be permitted to load at an increased draught of not more than 7 cm above the maximum permissible draught in effect as prescribed under 401.29(b) if it is equipped with a Draught Information System (DIS) and meets the following:

(1) An operational Draught Information System (DIS) approved by a member of the International Association of Classification Societies (IACS) as compliant with the Implementation Specifications found at *www.greatlakes-seaway.com* and having onboard;

(i) An operational AIS with accuracy approved by the Seaway; and

(ii) Up-to-date electronic charts; and

(iii) Up-to-date charts containing high resolution bathymetric data; and

(iv) Vessels must be equipped with a bow thruster and bow thruster must be operational.

(2) The DIS Tool Display shall be located as close to the primary conning position and be visible and legible.

(i) Verification document of the DIS must be kept on board the vessel at all times and made available for inspection;

(ii) DIS license to use the software must be valid;

(iii) A company letter attesting to officer training on use of the DIS must be kept on board and made available for inspection;

(iv) When transiting Seaway waters with the DIS, a trained officer on the use of the DIS must be on the bridge;

(v) Any vessel intending to use the DIS for the first time must notify the Manager or the Corporation in writing at least 24-hours prior to commencement of its initial transit in the System with the DIS in order to arrange for appropriate testing for approval to use the DIS;

(vi) Every navigation season, each vessel intending to use an approved DIS to transit the System must submit a completed confirmation checklist found at *www.greatlakes-seaway.com* to the Manager or the Corporation prior to its initial transit of the season;

(vii) If for any reason the DIS, AIS, or bow thruster becomes inoperable, malfunctions or is not used while the vessel is transiting at a draught greater than the maximum permissible draught prescribed under 401.29(b) in effect at the time, the vessel must notify the Manager or the Corporation immediately.

■ 7. Revise § 401.44 to read as follows:

§ 401.44 Mooring in locks.

(a) The primary means of securing vessels in the locks is by way of the Hands-Free Mooring (HFM) system. Vessels being moored by HFM must have a minimum of one well rested crew member on deck during the lockage to assist the Bridge team.

(b) Single tugs, tug/barge combinations, and small vessels (less than 160m in overall length) that are not eligible to use HFM are to be processed without mooring lines at the Canadian Locks with the exception of upbound lockages at Locks 4, 5 and 6 in the Welland Canal.

(c) Vessels requiring the use of mooring lines shall be processed as follows:

(1) Mooring lines shall only be placed on mooring posts as directed by the officer in charge of the mooring operation.

(2) No winch from which a mooring line runs shall be operated until the officer in charge of a mooring operation has signaled that the line has been placed on a mooring post.

(3) Once the mooring lines are on the mooring posts, lines shall be kept slack until the ''all clear'' signal is given by the lock personnel. When casting off signal is received, mooring lines shall be kept slack until the ''all clear'' signal is given by the lock personnel.

(4) Vessels being moored by ''Hands Free Mooring'' system (HFM) or passing through a lock without the use of mooring lines shall have a minimum of one well rested crew member on deck during the lockage to assist the Bridge team.

■ 8. Amend § 401.47 by revising paragraph (b) to read as follows:

§ 401.47 Leaving a lock.

* * * * *

(b) No vessel shall proceed out of a lock until the exit gates, ship arresters and the bridge, if any, are in a fully open position and the lock operator gives the ''all clear'' instruction.

* * * * *

■ 9. Amend § 401.57 by adding new paragraph (d) to read as follows:

§ 401.57 Disembarking or Boarding.

* * * * *

(d) Persons intending on disembarking or boarding a vessel shall only do so after they have confirmed with the Captain that the vessel is fully secured in the lock with Hands-Free Mooring or with mooring lines.

■ 10. Amend § 401.65 by revising paragraph (d) to read as follows:

§ 401.65 Communication—Ports, docks and anchorages.

* * * * *

(d) Every vessel intending to conduct a dive operation and/or Remotely Operated Vehicle (ROV) inspection at a dock, wharf or approach wall shall provide a 24-hour minimum notice of diving operations to the appropriate Seaway Traffic control Centre.

■ 11. Revise § 401.79 to read as follows:

§ 401.79 Advance notice of arrival, vessels requiring inspection.

(a) USCG Advance Notice of Arrival—All foreign flagged ships of 300 GRT or above intending to transit the Seaway shall submit one completed United States Coast Guard (USCG) Electronic Notice of Arrival (ENOA) prior to entering at call in point 2 (CIP 2) as follows:

(1) If your voyage time to CIP 2 is 96 hours or more, you must submit an ENOA 96 hours before entering the Seaway at CIP 2.

(2) If your voyage time to CIP 2 is less than 96 hours, you must submit an ENOA before departure, but at least 24 hours before entering the Seaway at CIP 2.

(3) If there are changes to the ENOA, submit them as soon as practicable but at least 12 hours before entering the Seaway at CIP 2.

(4) The NOA must be provided electronically following the USCG National Vessel Movement Center's (NVMC) procedures (*http://www.nvmc.uscg.gov*).

(5) To complete the ENOA correctly for Seaway entry, select the following:

(i) ''CIP 2'' as the Arrival Port,

(ii) ''Foreign to Saint Lawrence Seaway'' as the Voyage Type, and

(iii) ''Saint Lawrence Seaway Transit'' as the Arrival State, City and Receiving Facility.

(b) Foreign Vessel Inspection program:

(1) Enhanced Ship Inspections (ESI)—physical vessel inspection: Foreign flagged vessels are subject to a Seaway inspection once every two navigation seasons. Agents must provide an initial notice of inspection 120 hours prior to the ship's arrival at CIP2. (to: *inspecteursvm@seaway.ca* and to *vtc@dot.gov*).

(2) Subject to satisfactory performance, a Self-Inspection may be permitted in the interim season. Vessel to complete a Foreign Self Inspection report and submit electronically to *inspecteursvm@seaway.ca* and to *vtc@dot.gov.*

(3) The ESI or self-inspection is required on the first transit of the navigation season.

(4) Inland self-inspection: Inland domestic vessels which are approved by the Seaway and are ISM certified and have a company quality management system, must submit the ''Self-Inspection Report'', every 2 navigation seasons and not later than 30 days after ''fit out''.

(5) Inland domestic vessels not participating in the ''Self-Inspection Program'' are subject to Seaway inspection prior to every transit of the Seaway.

(6) Tug/barge combinations not on the ''Seaway Approved Tow'' list are subject to Seaway inspection prior to every transit of the Seaway unless provided with a valid Inspection Report for a round trip transit.

(7) A tall vessel, passenger vessel, or vessel of an unusual design is subject to Seaway yearly inspection.

■ 12. Amend § 401.84 by redesignating paragraphs (d) through (g) as paragraphs (e) through (h) and add new paragraph (d) to read as follows:

* * * * *

(d) any malfunction on the vessel of equipment and machinery that is noted as operational in the current ''Enhanced Ship Inspection'' or ''Self Inspection'' of the vessel;

* * * * *

Issued at Washington, DC, under authority delegated at 49 CFR part 1.101.

Great Lakes St. Lawrence Seaway Development Corporation.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2024–04744 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–61–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0588; FRL–11585–02–R9]

Air Plan Revisions; California; Sacramento Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Sacramento Metropolitan Air Quality Management District (SMAQMD) portion of the California State Implementation Plan (SIP). This revision concerns a rule submitted to address section 185 of the Clean Air Act (CAA or the Act).

DATES: This rule is effective April 5, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2023–0588. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Mae Wang, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; phone: (415) 947–4137; email: *wang.mae@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On December 15, 2023 (88 FR 86870), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
SMAQMD	307	Clean Air Act Penalty Fees	03/23/2023	5/11/2023

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving SMAQMD Rule 307 into the California SIP. The March 23, 2023 version of Rule 307 will replace the

previously approved version of this rule in the SIP. This final approval action also removes the EPA's obligation to promulgate a Federal Implementation Plan (FIP) for the SMAQMD portion of the Sacramento Metro ozone nonattainment area by permanently stopping the FIP clock associated with the January 17, 2023 (88 FR 2541) finding of failure to submit.[1]

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of SMAQMD Rule 307, ''Clean Air Act Penalty Fees,'' amended on March 23, 2023, which addresses the CAA section 185 fee program requirements. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.S. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 6, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 26, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(308)(i)(C)(*2*) and (c)(610) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(308) * * *

(i) * * *

(C) * * *

(*2*) Previously approved on August 26, 2003, in paragraph (c)(308)(i)(C)(*1*) of this section and now deleted with replacement in paragraph

[1] The sanctions clocks associated with the January 17, 2023 action were previously stopped by our completeness finding on November 6, 2023, for the SMAQMD portion of the Sacramento Metro area.

(c)(610)(i)(A)(*1*) of this section: Rule 307, adopted on September 26, 2002.

* * * * *

(610) The following regulations were submitted electronically on May 11, 2023, by the Governor's designee as an attachment to a letter dated May 10, 2023.

(i) *Incorporation by reference.* (A) Sacramento Metropolitan Air Quality Management District.

(*1*) Rule 307, ''Clean Air Act Penalty Fees,'' amended on March 23, 2023.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

* * * * *

[FR Doc. 2024–04708 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 89, No. 45
Wednesday, March 6, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0457; Project Identifier MCAI–2023–01207–T]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–02–10, which applies to certain Dassault Aviation Model FALCON 7X, FALCON 900EX, and FALCON 2000EX airplanes. AD 2022–02–10 requires replacement of certain titanium screws. Since the FAA issued AD 2022–02–10, affected parts have been found in other areas of certain Falcon 7X airplanes as well as in additional Falcon 7X airplanes. This proposed AD would continue to require the actions in AD 2022–02–10, add other locations for screw replacement, and revise the applicability, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by April 22, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0457; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For the EASA AD identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu*. It is also available at *regulations.gov* under Docket No. FAA–2024–0457.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0457; Project Identifier MCAI–2023–01207–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–02–10, Amendment 39–21907 (87 FR 7025, February 8, 2022) (AD 2022–02–10), for certain Dassault Aviation Model FALCON 7X, FALCON 900EX, and FALCON 2000EX airplanes. AD 2022–02–10 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2021–0047, dated February 16, 2021, to correct an unsafe condition.

AD 2022–02–10 requires replacement of certain titanium screws. The FAA issued AD 2022–02–10 to address failure of an affected screw installed in a critical location, possibly resulting in reduced structural integrity of the airplane. See the MCAI for additional background information.

Actions Since AD 2022–02–10 Was Issued

Since the FAA issued AD 2022–02–10, EASA superseded EASA AD 2021–

0047, dated February 16, 2021, and issued EASA AD 2023–0207, dated November 21, 2023 (also referred to as the MCAI), to correct an unsafe condition for certain Dassault Aviation Model FALCON 7X, FALCON 900EX, and FALCON 2000EX airplanes. The MCAI states that since EASA issued AD 2021–0047, it was determined that affected parts have been installed in production in additional areas of certain Model FALCON 7X airplanes already included in the applicability of EASA AD 2021–0047. Additionally, it was determined that additional Model FALCON 7X airplanes were not included in the applicability of EASA AD 2021–0047.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0457.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2022–02–10, this proposed AD would retain all of the requirements of AD 2022–02–10. Those requirements are referenced in EASA AD 2023–0207, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0207 specifies procedures for replacing titanium screws.

Dassault Service Bulletin 7X–467, Revision 2, dated March 20, 2023, specifies procedures for additional work.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2022–02–10. This proposed AD would require accomplishing the actions specified in EASA AD 2023–0207 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0207 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0207 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0207 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0207. Service information required by EASA AD 2023–0207 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–0457 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 44 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2022–02–10.	Up to 90 work-hours × $85 per hour = $7,650.	$0	Up to $7,650	Up to $336,600.
New proposed requirements ..	Up to 110 work-hours × $85 per hour = $9,350.	0	Up to $9,350	Up to $411,400.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–02–10, Amendment 39–21907 (87 FR 7025, February 8, 2022); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2024–0457; Project Identifier MCAI–2023–01207–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by April 22, 2024.

(b) Affected ADs

This AD replaces AD 2022–02–10, Amendment 39–21907 (87 FR 7025, February 8, 2022) (AD 2022–02–10).

(c) Applicability

This AD applies to Dassault Aviation airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2023–0207, dated November 21, 2023 (EASA AD 2023–0207).

(1) Model FALCON 7X airplanes.

(2) Model FALCON 900EX airplanes.

(3) Model FALCON 2000EX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 51, Standard Practices/Structures.

(e) Unsafe Condition

This AD was prompted by a report of an improper heat treatment process applied during the manufacturing of certain Decomatic titanium screws, and by the determination that affected parts in additional areas on certain airplanes, as well as additional airplanes, are subject to the unsafe condition. The FAA is issuing this AD to address failure of an affected screw installed in a critical location, possibly resulting in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0207.

(h) Exceptions to EASA AD 2023–0207

(1) Where EASA AD 2023–0207 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0207.

(3) Where Ref Publications specifies ''Dassault SB 7X–467 original issue dated 16 November 2020, Rev. 1 dated 12 December 2022 or Rev. 2 dated 20 March 2023,'' this AD requires replacing those words with ''Dassault Service Bulletin 7X–467, Revision 2, dated March 20, 2023.''

(i) Credit for Previous Actions

For Model FALCON 7X airplanes: This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Dassault Service Bulletin 7X–467, dated November 16, 2020, provided the additional work specified in Dassault Service Bulletin 7X–467, Revision 2, dated March 20, 2023, is accomplished within the applicable compliance time specified in EASA AD 2023–0207.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0207, dated November 21, 2023.

(ii) Dassault Service Bulletin 7X–467, Revision 2, dated March 20, 2023.

(3) For EASA AD 2023–0207, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on February 28, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–04563 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, and 270

[EPA–HQ–OLEM–2023–0085; FRL 9247–03–OLEM]

RIN 2050–AH27

Definition of Hazardous Waste Applicable to Corrective Action for Releases From Solid Waste Management Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending, until March 26, 2024, the comment period for the proposed rule published in the **Federal Register** on February 8, 2024. The proposed rule would amend the definition of hazardous waste applicable to corrective action to address releases from solid waste management units at RCRA-permitted treatment, storage, and disposal facilities and make related conforming amendments, thereby

providing clear regulatory authority to fully implement the Resource Conservation and Recovery Act (RCRA) statutory requirement that permitted facilities conduct corrective action to address releases not only of substances listed or identified as hazardous waste in the regulations but of any substance that meets the statutory definition of hazardous waste. The proposed rule would also provide notice of EPA's interpretation that the statutory definition of hazardous waste applies to corrective action for releases from solid waste management units at permitted and interim status facilities.

DATES: The public comment period for the proposed rule published in the **Federal Register** (FR) on February 8, 2024 (89 FR 8598), originally ending March 11, 2024, is being extended by 15 days. Written comments must be received on or before March 26, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2023–0085, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, RCRA Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2023–0085, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section of this document. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Barbara Foster, Program Information and Implementation Division, Office of Resource Conservation and Recovery (5303T)) Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460, 202–566–0382, *foster.barbara@epa.gov.*

SUPPLEMENTARY INFORMATION: On February 8, 2024, the Agency published in the **Federal Register** (89 FR 8598) a proposed rule that would amend the regulations applicable to RCRA treatment, storage, and disposal facilities in two related respects. First, it would amend the definition of hazardous waste applicable to corrective action. Specifically, it would amend the definition in § 260.10 to expressly apply the RCRA section 1004(5) statutory definition of hazardous waste to corrective action requirements under § 264.101 and 40 CFR part 264 Subpart S. Similarly, it would amend the identical definition in the hazardous waste facility permitting regulations, § 270.2, to expressly apply the statutory definition of hazardous waste to the requirements relating to corrective action in § 270.14(d). These proposed revisions would more clearly provide EPA authority to address, through corrective action for solid waste management units, releases of the full universe of substances that the statute intended—not only hazardous waste and hazardous constituents listed or identified in the regulations, but all substances that meet the definition of hazardous waste in RCRA section 1004(5) at a facility. These proposed amendments are consistent with EPA's longstanding interpretation of the RCRA statute.

Second, this proposed rule would add RCRA sections 3004(u) and (v) and 3008(h) to the statutory authorities identified in § 261.1(b)(2). That section provides that the statutory definitions of solid and hazardous waste govern the scope of EPA's authority under certain sections of RCRA, not the more limited 40 CFR part 261 regulatory definitions. These revisions provide notice of and codify the Agency's interpretation of the statute—that it provides authority to address releases from solid waste management units of all substances that meet the definition of hazardous waste under the statute.

Following publication of the proposed rule, several members of the public requested that the Agency extend the comment period.

In response to these requests, the Agency is extending the comment period for 15 days, until March 26, 2024. EPA does not want to unnecessarily delay this rulemaking and believes that this 15-day extension provides more than adequate time for reviewers to review the proposed rule and to submit comments given the very narrow scope of the rulemaking, and the limited amount of material reviewers need to review.

Dated: February 28, 2024.

Carolyn Hoskinson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2024–04712 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 89, No. 45
Wednesday, March 6, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Agency Information Collection Activities: Submission to the Office of Management and Budget for Review and Approval; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Agency for International Development (USAID).

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Information Collection Review procedures of the Paperwork Reduction Act of 1995 (PRA), the United States Agency for International Development (USAID), is seeking comment on the proposed Generic Clearance for the Collection of Qualitative Customer Feedback on Agency Service Delivery. The Agency will use surveys and forms for routine customer feedback to collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of the current services, information, and to make improvements in customer service.

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Kelly Hamilton at 202–921–5016, *icrteam@usaid.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the PRA, the Agency is publishing this Notice to inform the public that the Agency will submit this proposed collection to the Office of Management and Budget (OMB) for approval. The Agency previously published this proposed information collection in the **Federal Register** on October 31, 2023 (88 FR 74401) with a 60-day comment period. The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of the current services, information, and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, procedures outlined in Question 16 will be followed);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide remunerations for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

The projected average annual burden estimates for the next three years are listed below. The burdens have been increased from the 60-day notice amounts due to internal agency discussions on expected needs.

Estimated Annual Number of Respondents: 200,000.

Responses per Respondent: 1.

Annual Responses: 200,000.

Average Minutes per Response: 15 minutes.

Annual Burden Hours: 50,000 hours.

Frequency: On occasion.

Dated: February 29, 2024.

Taniesha D. Tolbert,

Supervisory Records Information Management Specialist, Bureau for Management, Office of Management Services, Information and Records Division.

[FR Doc. 2024–04650 Filed 3–5–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by April 5, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Institute of Food and Agriculture

Title: Reporting Requirements for State Plans of Work for Agricultural Research and Extension Formula Funds.

OMB Control Number: 0524–0036.

Summary of Collection: Section 202 and 225 of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA) which requires that a plan of work must be submitted by each institution and approved by the National Institute of Food and Agriculture (NIFA) before formula funds may be provided to the 1862 and 1890 land-grant institutions. The plan of work must address critical agricultural issues in the State and describe the programs and project targeted to address these issues using the NIFA formula funds. The plan of work also must describe the institution's multistate activities as well as their integrated research and extension activities. NIFA is requesting to continue to collect an update to the 5-Year Plan of Work which began with the Fiscal Year 2007, and as a result no longer needs to collect the initial 5-Year Plan. Also, as required by the Food Conservation and Energy Act of 2008 (FCEA) (*Pub. L. 110–246,* sec. 7505), NIFA is working with the university partners in extension and research to review and identify measures to streamline the submission, reporting under, and implementation of plan of work requirements.

Need and Use of the Information: Institutions are required to annually report to NIFA the following: (1) The actions taken to seek stakeholder input to encourage their participation; (2) a brief statement of the process used by the recipient institution to identify individuals or groups who are stakeholders and to collect input from them; and (3) a statement of how collected input was considered. NIFA uses the information to provide feedback to the institutions on their Plans of Work and Annual Reports of Accomplishments and Results in order for institutions to improve the conduct and the delivery of their programs.

Failure to comply with the requirements may result in the withholding of a recipient institution's formula funds and redistribution of its share of formula funds to other eligible institutions.

Description of Respondents: Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 100.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 172,464.

Rachelle Ragland-Greene,

Acting Departmental Information Collection Clearance Officer.

[FR Doc. 2024–04678 Filed 3–5–24; 8:45 am]

BILLING CODE 3410–9–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–9–2024]

Foreign-Trade Zone 98; Application for Subzone Expansion; Hyster-Yale Group, Inc.; Sulligent, Alabama

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of Birmingham, grantee of FTZ 98, requesting an expansion of Subzone 98D for the facility of Hyster-Yale Group, Inc. (Hyster-Yale), located in Sulligent, Alabama. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on March 1, 2024.

The application requests authority to expand Subzone 98D to include the following new site: Site 3 (6.2 acres) is located at 7862 Highway 278, Sulligent, Alabama. No authorization for additional production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Kolade Osho of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is April 15, 2024. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 30, 2024.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Kolade Osho at *Kolade.Osho@trade.gov.*

Dated: March 1, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–04746 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–502]

Circular Welded Carbon Steel Pipes and Tubes From Thailand: Preliminary Results and Rescission, in Part, of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain producers/exporters subject to this administrative review did not make sales of subject merchandise at less than normal value (NV) during the period of review (POR) March 1, 2022, through February 28, 2023. Commerce is also rescinding the review, in part, with respect to 28 respondents. We invite interested parties to comment on these preliminary results.

DATES: Applicable March 6, 2024.

FOR FURTHER INFORMATION CONTACT: Jacob Keller or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4849 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 11, 1986, Commerce published in the **Federal Register** the antidumping duty order on circular welded carbon steel pipes and tubes (CWP) from Thailand.[1] On March 2, 2023, Commerce published in the **Federal Register** the notice of initiation of the administrative review of the *Order*.[2] On June 5, 2023, Commerce selected Saha Thai Steel Pipe Public Co., Ltd. (Saha Thai) and Thai Premium Pipe Co. Ltd. (TPP) for individual examination as the mandatory respondents in this administrative review.[3] On January 16, 2024, Commerce notified interested parties of our intent to rescind this administrative review with respect to the 28 companies that have no reviewable suspended entries.[4] On November 13, 2023, Commerce extended the time limit for these preliminary results to March 5, 2024.[5] For a complete description of the events that occurred since the initiation of this review, *see* the Preliminary Decision Memorandum.[6]

A list of topics discussed in the Preliminary Decision Memorandum is attached in Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by the *Order* are CWP from Thailand. For a complete description of the scope of this *Order, see* the Preliminary Decision Memorandum.

Rescission of Review, In Part

Pursuant to 19 CFR 351.213(d)(3), Commerce will rescind an administrative review when there are no reviewable suspended entries. Based on our analysis of U.S. Customs and Border Protection (CBP) information, we preliminarily determine that 28 companies had no entries of subject merchandise during the POR. On January 16, 2024, we notified parties of our intent to rescind this administrative review with respect to the 28 companies listed in Appendix II that had no reviewable suspended entries during the POR.[7] No parties commented on our Intent to Rescind Memorandum. As a result, we are rescinding this review, in part, with respect to the 28 companies listed in Appendix II of this notice.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). We calculated export price and NV in accordance with sections 772 and 773 of the Act, respectively. For a complete description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist for the period March 1, 2022, through February 28, 2023:

Producer or exporter	Weighted-average dumping margin (percent)
Saha Thai Steel Pipe Public Co., Ltd. (also known as Saha Thai Steel Pipe (Public) Company, Ltd.)	0.00
Thai Premium Pipe Co. Ltd.	0.00

Assessment Rates

Upon completion of the final results, Commerce shall determine and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[8] If Saha Thai or TPP's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[9] If either the respondent's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP not to liquidate relevant entries without regards to antidumping duties.

For entries of subject merchandise during the POR produced by Saha Thai or TPP for which they did not know that the merchandise was destined to the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[10]

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the

[1] *See Antidumping Duty Order; Circular Welded Carbon Steel Pipes and Tubes from Thailand,* 51 FR 8341 (March 11, 1986) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881, 29884 (May 9, 2023).

[3] *See* Memorandum, ''Respondent Selection,'' dated June 5, 2023.

[4] *See* Memorandum, ''Intent to Partially Rescind Review,'' dated January 16, 2024 (Intent to Rescind Memorandum).

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of the Antidumping Duty Administrative Review; 2021–2022,'' dated November 7, 2022.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review and Rescission, in Part, of the Antidumping Duty Order on Circular Welded Carbon Steel Pipes and Tubes from Thailand; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* Intent to Rescind Memorandum.

[8] *See* 19 CFR 351.212(b)(1).

[9] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[10] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired, *i.e.,* within 90 days of publication.

The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[11]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of final results of administrative review for all shipments of CWP from Thailand entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Saha Thai and TPP will be equal to the weighted-average dumping margin established in the final results of this review (except, if that rate is *de minimis* within the meaning of 19 CFR 351.106(c)(1), then the cash deposit rate will be zero); (2) for merchandise exported by a company not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review or another completed segment of this proceeding, but the producer is, then the cash deposit rate will be the company-specific rate established for the completed segment for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 15.67 percent, the all-others rate established in the less-than-fair-value investigation.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days after the date of publication of this notice.[13] Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[14] Interested parties who submit case or rebuttal briefs in this administrative review must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[15]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[16] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the case and rebuttal briefs.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[17] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[18]

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

Dated: February 29, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Companies Rescinded From This Administrative Review

1. Apex International Logistics
2. Aquatec Maxcon Asia
3. Asian Unity Part Co., Ltd.

[11] *See* section 751(a)(2)(C) of the Act; and 19 CFR 351.212(b).

[12] *See Order.*

[13] *See* 19 CFR 351.224(b).

[14] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Final Service Rule*).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2).

[16] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[17] *See* 19 CFR 351.303.

[18] *See APO and Final Service Rule.*

4. Better Steel Pipe Company Limited
5. Bis Pipe Fitting Industry Co., Ltd.
6. Blue Pipe Steel Center Co. Ltd.
7. Chuhatsu (Thailand) Co., Ltd.
8. CSE Technologies Co., Ltd.
9. Expeditors International (Bangkok)
10. Expeditors Ltd.
11. FS International (Thailand) Co., Ltd.
12. Kerry-Apex (Thailand) Co., Ltd.
13. K Line Logistics
14. Oil Steel Tube (Thailand) Co., Ltd.
15. Otto Ender Steel Structure Co., Ltd.
16. Pacific Pipe and Pump
17. Pacific Pipe Public Company Limited
18. Panalpina World Transport Ltd.
19. Polypipe Engineering Co., Ltd.
20. Schlumberger Overseas S.A.
21. Siam Fittings Co., Ltd.
22. Siam Steel Pipe Co., Ltd.
23. Sino Connections Logistics (Thailand) Co., Ltd.
24. Thai Malleable Iron and Steel
25. Thai Oil Group
26. Thai Oil Pipe Co., Ltd.
27. Vatana Phaisal Engineering Company
28. Visavakit Patana Corp., Ltd.

[FR Doc. 2024–04740 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–838]

Clad Steel Plate From Japan: Final Results of the Expedited Fifth Sunset Review of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on clad steel plate from Japan would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Expedited Sunset Review'' section of this notice.

DATES: Applicable March 6, 2024.

FOR FURTHER INFORMATION CONTACT: Genevieve Coen, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3251.

SUPPLEMENTARY INFORMATION:

Background

On July 2, 1996, Commerce published in the **Federal Register** the AD order on clad steel plate from Japan.[1] On November 1, 2023, Commerce published the initiation of the fifth sunset review of the *Order* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] In accordance with 19 CFR 351.218(d)(1)(i) and (ii), Commerce received a notice of intent to participate in this sunset review from NobelClad (the domestic interested party) within 15 days after the date of publication of the *Initiation Notice*.[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act as a producer of a domestic like product in the United States.

Commerce received a timely, adequate substantive response to the *Initiation Notice* from the domestic interested party within the 30-day period specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive substantive responses from any other interested parties, and no party requested a hearing.

On December 21, 2023, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from other interested parties.[5] As a result, in accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited, *i.e.,* 120-day, sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is all clad steel plate from Japan of a width of 600 millimeters (mm) or more and a composite thickness of 4.5 mm or more. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum, including the likelihood of continuation or recurrence of dumping and the magnitude of the margin of dumping likely to prevail if the *Order* were revoked.[7] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would likely lead to the continuation or recurrence of dumping and that the magnitude of the margin of dumping likely to prevail would be at a rate up to 118.53 percent.[8]

Administrative Protective Order

This notice serves as the only reminder to interested parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing the results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: February 29, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–04739 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Notice of Antidumping Order: Clad Steel Plate from Japan,* 61 FR 34421 (July 2, 1996) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 74977 (November 1, 2023) (*Initiation Notice*).

[3] *See* Domestic Interested Party's Letter, ''Notice of Intent to Participate,'' dated November 15, 2023.

[4] *See* Domestic Interested Party's Letter, ''NobelClad's Substantive Response to Notice of Initiation,'' dated November 29, 2023.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2023,'' dated October 25, 2023.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Fifth Sunset Review of the Antidumping Duty Order on Clad Steel Plate from Japan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *Id.*

[8] *Id.* at 8–10.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–823–819]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Ukraine: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that seamless carbon and alloy steel standard, line, and pressure pipe (seamless pipe) from Ukraine was sold at prices below normal value during the period of review (POR) February 10, 2021, through July 31, 2022.

DATES: Applicable March 6, 2024.

FOR FURTHER INFORMATION CONTACT: Reginald Anadio, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3166.

SUPPLEMENTARY INFORMATION:

Background

On September 7, 2023, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register**.[1] Interpipe,[2] the sole mandatory respondent under review, and the domestic interested party Vallourec Star, L.P. (Vallourec), each submitted comments on the *Preliminary Results*.[3] For a description of the events since the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results of review, *see* the Issues and Decision Memorandum.[4] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [5]

The merchandise covered by the scope of the *Order* is seamless pipe from Ukraine. For a full description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in Interpipe's case brief and Vallourec's rebuttal brief are addressed in the Issues and Decision Memorandum. A list of these issues is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

We determine that the following weighted-average dumping margin exists for the period February 10, 2021, through July 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Interpipe Ukraine LLC/LJSC Interpipe Niznedneprovsky Tube Rolling Plant/LLC Interpipe Niko Tube/ Interpipe Europe S.A.	4.99

Disclosure

Because Commerce made no changes to the *Preliminary Results,* we have not modified our preliminary weighted-average dumping margin calculation. We are adopting the *Preliminary Results* as the final results of this review. Consequently, there are no calculations to disclose in accordance with 19 CFR 351.224(b) for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review.[6] We will calculate importer-specific *ad valorem* assessment rates for the merchandise by dividing the total amount of antidumping duties calculated for all reviewed sales to the importer by the total entered value of the merchandise sold to the importer, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[7]

In accordance with Commerce's ''automatic assessment'' practice, we will instruct CBP to liquidate POR entries of subject merchandise which Interpipe produced and sold but did not know was destined for the United States, at the all-others rate (*i.e.,* 23.75 percent) [8] if there is no rate for the intermediate company(ies) involved in the transaction.[9]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register**, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Interpipe will be equal to the weighted-average dumping margin listed in the table above; (2) for companies that were previously reviewed or investigated in this proceeding that are not listed in the table above, the cash deposit rate will continue to be the rate assigned to the company in the most recently

[1] *See Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Ukraine: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022* 88 FR 61503 (September 7, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] Interpipe refers to the collapsed entity, Interpipe Ukraine LLC, PJSC Interpipe Niznedneprovsky Tube Rolling Plant, LLC Interpipe Niko Tube, and Interpipe Europe S.A. *See Preliminary Results* PDM at the sections titled ''Summary'' and ''Affiliation/Single Entity.''

[3] *See* Interpipe's Letter, ''Case Brief for Interpipe,'' dated October 10, 2023; *see also* Vallourec's Letter, ''Petitioner's Rebuttal Brief,'' dated October 17, 2023.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2021–2022 Administrative Review of the Antidumping Duty Order on Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Ukraine,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from the Republic of Korea, the Russian Federation, and Ukraine: Antidumping Duty Orders,* 86 FR 47055 (August 23, 2021) (*Order*).

[6] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

[7] *Id.,* 77 FR 8101, 8102; *see also* 19 CFR 351.106(c)(2).

[8] *See Order,* 86 FR 47055.

[9] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

completed segment of this proceeding in which the company was examined; (3) if the exporter of the subject merchandise does not have a company-specific rate but the producer of the subject merchandise does, then the cash deposit rate will be the rate assigned to the producer of the subject merchandise in the most recently completed segment of this proceeding in which the producer was examined; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 23.75 percent that was established in the less-than-fair-value investigation in this proceeding.[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results of review in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

[10] *See Order,* 84 FR at 47057.

Dated: February 29, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–04707 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

RIN 0693–XA10

Proposed Revision to Voluntary Product Standard (PS) 20–20 ''American Softwood Lumber Standard''

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice and request for comments.

SUMMARY: This notice advises the public that the National Institute of Standards and Technology (NIST) is seeking comments for the proposed revision of Voluntary Product Standard (PS) 20–20, ''American Softwood Lumber Standard.'' This standard, prepared by the American Lumber Standard Committee, serves the procurement and regulatory needs of numerous Federal, State, and local government agencies by providing for uniform, industry-wide grade-marking and inspection requirements for softwood lumber. The implementation of the standard also allows for uniform labeling and auditing of treated wood and, through a Memorandum of Understanding with the U.S. Department of Agriculture, labeling and auditing of wood packaging materials for international trade. As part of a five-year review process, NIST is seeking public comment and invites interested parties to review the revised standard and submit comments.

DATES: Written comments regarding the proposed revision, PS 20–25, should be submitted to the Standards Coordination Office, NIST, no later than April 22, 2024.

ADDRESSES: An electronic copy (in PDF) of the current standard, PS 20–20, can be obtained at the following website *https://www.nist.gov/standardsgov/voluntary-product-standards-program.* Written comments on the standard should be submitted to Nathalie Rioux via email to *standards@nist.gov* or via mail to Standards Coordination Office, NIST, 100 Bureau Drive, Stop 2150, Gaithersburg, MD 20899–2150.

FOR FURTHER INFORMATION CONTACT: Nathalie Rioux, Standards Coordination Office, National Institute of Standards and Technology, email: *standards@nist.gov.*

SUPPLEMENTARY INFORMATION: Under Department of Commerce regulations codified in title 15, Code of Federal Regulations, part 10, *Procedures for the Development of Voluntary Product Standards,* and administered by NIST, the American Lumber Standard Committee acts as the Standing Committee for PS 20–20, *American Softwood Lumber Standard,* responsible for maintaining, revising, and interpreting the standard. The Committee is comprised of producers, distributors, users, and others with an interest in the standard.

Voluntary Product Standard (PS) 20–20 establishes standard sizes and requirements for developing and coordinating the lumber grades of the various species of lumber, the assignment of design values, and the preparation of grading rules applicable to each species. Its provisions include implementation of the standard through an accreditation and certification program; establishment of principal trade classifications and lumber sizes for yard, structural, and factory/shop use; classification, measurement, grading, and grade-marking of lumber; definitions of terms and procedures to provide a basis for the use of uniform methods in the grading inspection, measurement, and description of softwood lumber; commercial names of the principal softwood species; definitions of terms used in describing standard grades of lumber; and commonly used industry abbreviations. The standard also includes the organization and functions of the American Lumber Standard Committee, the Board of Review, and the National Grading Rule Committee.

All public comments will be reviewed and considered. All comments, including attachments will be accepted in Microsoft word, or Adobe PDF formats. Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish comments publicly, unedited and in their entirety. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Comments will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Written comments should be submitted in accordance with the **DATES** and **ADDRESSES** sections of this notice. The American Lumber Standard Committee and NIST will consider all responsive comments received and may revise the standard as appropriate.

Tamiko Ford,

NIST Executive Secretariat.

[FR Doc. 2024–04741 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Internet of Things Advisory Board

AGENCY: National Institute of Standards and Technology (NIST).

ACTION: Notice of open meeting.

SUMMARY: The Internet of Things (IoT) Advisory Board will meet Tuesday, April 2 and Wednesday, April 3, 2024 from 11 a.m. until 5 p.m., eastern time. Both sessions will be open to the public.

DATES: The Internet of Things (IoT) Advisory Board will meet Tuesday, April 2 and Wednesday, April 3, 2024 from 11a.m. until 5 p.m., eastern time.

ADDRESSES: The meeting will be virtual via Webex webcast hosted by the National Cybersecurity Center of Excellence (NCCoE) at NIST. Please note registration instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Barbara Cuthill, Information Technology Laboratory, National Institute of Standards and Technology, Telephone: (301) 975–3273, Email address: *barbara.cuthill@nist.gov.*

SUPPLEMENTARY INFORMATION:

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1001 *et seq.,* notice is hereby given that the IoT Advisory Board will hold open meetings on the dates and times indicated in the **DATES** section. These sessions will be open to the public. The IoT Advisory Board is authorized by section 9204(b)(5) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) and advises the IoT Federal Working Group convened by the Secretary of Commerce pursuant to Section 9204(b)(1) of the Act on matters related to the Federal Working Group's activities. Details regarding the IoT Advisory Board's activities are available at *https://www.nist.gov/itl/applied-cybersecurity/nist-cybersecurity-iot-program/internet-things-advisory-board.*

The agenda for the April, 2024 meeting is expected to focus on finalizing the IoT Advisory Board's report for the IoT Federal Working Group and the recommendations in that report.

The recommendations and discussions are expected to focus on the specific focus areas for the report cited in the legislation and the charter:

- Smart traffic and transit technologies
- Augmented logistics and supply chains
- Sustainable infrastructure
- Precision agriculture
- Environmental monitoring
- Public safety
- Health care

In addition, the IoT Advisory Board may discuss other elements that the legislation called for in the report:

- whether adequate spectrum is available to support the growing Internet of Things and what legal or regulatory barriers may exist to providing any spectrum needed in the future;
- policies, programs, or multi-stakeholder activities that—
  - promote or are related to the privacy of individuals who use or are affected by the Internet of Things;
  - may enhance the security of the Internet of Things, including the security of critical infrastructure;
  - may protect users of the Internet of Things; and
  - may encourage coordination among Federal agencies with jurisdiction over the Internet of Things

Note that agenda items may change without notice. The final agendas will be posted on the IoT Advisory Board web page: *https://www.nist.gov/itl/applied-cybersecurity/nist-cybersecurity-iot-program/internet-things-advisory-board.*

Public Participation: Written comments and requests to present comments orally to the IoT Advisory Board from the public are invited and may be submitted electronically by email to Barbara Cuthill at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. on the Tuesday, March 26, 2024 to allow distribution of written comments to IoT Advisory Board members prior to the meeting.

Each IoT Advisory Board meeting agenda will include a period, not to exceed sixty minutes, for oral presentation of comments from the public. Oral presentation of comments from the public during this sixty-minute period will be accommodated on a first-come, first-served basis and limited to five minutes per person for oral presentation if requested by the commenter.

Members of the public who wish to expand upon their submitted comments, those who had wished to present comments orally but could not be accommodated on the agenda, and those who were unable to attend the meeting via webinar, are invited to submit written statements. In addition, written statements are invited and may be submitted to the IoT Advisory Board at any time. All written statements should be directed to the IoT Advisory Board Secretariat, Information Technology Laboratory by email to: *Barbara.Cuthill@nist.gov.*

Admittance Instructions: Participants planning to attend via webinar must register via the instructions found on the IoT Advisory Board's web page at h*ttps://www.nist.gov/itl/applied-cybersecurity/nist-cybersecurity-iot-program/internet-things-advisory-board.*

Tamiko Ford,

NIST Executive Secretariat.

[FR Doc. 2024–04738 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD733]

Fisheries of the South Atlantic, Gulf of Mexico, and Caribbean; Southeast Data, Assessment, and Review (SEDAR) Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of the SEDAR Steering Committee meeting.

SUMMARY: The SEDAR Steering Committee will meet to discuss the SEDAR stock assessment process and assessment schedule. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR Steering Committee will meet Monday, March 25, 2024, from 1 p.m. until 6 p.m., eastern and from 9 a.m. until 3 p.m., eastern on Tuesday, March 26, 2024. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the SEDAR process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The SEDAR Steering Committee meeting will be held at the Doubletree by Hilton, 5264 International Blvd., North Charleston, SC 29418; phone: (843) 576–0300.

SEDAR address: 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Program Manager, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The SEDAR Steering Committee provides guidance and oversight of the SEDAR stock assessment program and manages assessment scheduling.

The items of discussion for this meeting are as follows:

SEDAR Projects Update
SEDAR Projects Schedule
SEDAR Process Review and Discussions
Other Business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 1, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–04749 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD585]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Whittier Head of the Bay Cruise Dock Project

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments on proposed renewal incidental harassment authorization.

SUMMARY: NMFS received a request from Turnagain Marine Construction (TMC) for the renewal of their currently active incidental harassment authorization (IHA) to take marine mammals incidental to the cruise dock construction project in Whittier, Alaska. TMC's activities consist of activities that are covered by the current authorization but will not be completed prior to its expiration. Pursuant to the Marine Mammal Protection Act (MMPA), prior to issuing the currently active IHA, NMFS requested comments on both the proposed IHA and the potential for renewing the initial authorization if certain requirements were satisfied. The renewal requirements have been satisfied, and NMFS is now providing an additional 15-day comment period to allow for any additional comments on the proposed renewal not previously provided during the initial 30-day comment period.

DATES: Comments and information must be received no later than March 21, 2024.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, and should be submitted via email to *ITP.harlacher@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. Attachments to comments will be accepted in Microsoft Word, Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jenna Harlacher, Office of Protected Resources (OPR), NMFS, (301) 427–8401. Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses

(referred to here as ''mitigation measures''). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in the MMPA and the NMFS's implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed one year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal of an IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned; or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA);

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and
- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized; and

3. Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals.* Any comments received on the potential renewal, along with relevant comments on the initial IHA, have been considered in the development of this proposed IHA renewal, and a summary of agency responses to applicable comments is included in this notice. NMFS will consider any additional public comments prior to making any final decision on the issuance of the requested renewal, and agency responses will be summarized in the final notice of our decision.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA renewal) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically excluded from further NEPA review. NMFS has preliminarily determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

History of Request

On March 29, 2023, NMFS issued an IHA to TMC to take marine mammals incidental to the construction of the cruise ship dock in Whittier, Alaska (88 FR 19927, April 4, 2023), effective from April 1, 2023 through March 31, 2024. On November 16, 2023, NMFS received an application for the renewal of that initial IHA. As described in the application for renewal IHA, the activities for which incidental take is requested consist of activities that are covered by the initial authorization but will not be completed prior to its expiration. As required, the applicant also provided a preliminary monitoring report which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted.

Description of the Specified Activities and Anticipated Impacts

TMC's planned cruise ship construction project was planned to cover a 12-month window during which approximately 129 days of pile-installation and -removal activity will occur. This project involved installation and removal of seventy-two 36-inch (in) (0.91-meter (m)) temporary steel pile guides and installation of thirty-six 36-in (0.91-m), sixteen 42-in (1.1-m), and twenty 48-in (1.2-m) permanent steel piles. Three different installation methods were planned to be used including vibratory installation of piles into dense material, impact pile driving to drive piling to tip elevation, and the Down-the-Hole (DTH) hammer to drill pile into the bedrock. TMC planned to deploy a bubble curtain to the 60-foot (ft) (18.3-m) isobath. This was planned to be used during all activities that fall below the 60-ft (18.3-m) isobath.

Due to unexpected winter weather conditions causing slower construction, TMC will not complete the initial construction during the 1-year period. Specifically, at the time of the renewal request, TMC had completed installation of 51 permanent piles to construct the approach trestle, 2 float restraint dolphins, and most of the mooring trestle. With the remaining time under the initial IHA, TMC anticipates completing at a minimum installation of 10 additional permanent piles.

This renewal request is to cover the subset of the activities covered in the initial IHA that will not be completed during the effective IHA period. TMC plans to complete the remaining

construction activities, which would include at maximum installation of four 48-in piles for one mooring dolphin, installation of seven 36-in piles for the remainder of the mooring trestle, and installation and removal of eleven 36-in temporary piles to guide installation of the remaining permanent piles.

The likely or possible impacts of the TMC's proposed activity on marine mammals could involve both non-acoustic and acoustic stressors and is unchanged from the impacts described in the initial IHA. Potential non-acoustic stressors could result from the physical presence of the equipment, vessels, and personnel; however, any impacts to marine mammals are expected to primarily be acoustic in nature. Sounds resulting from pile installation, removal, and drilling may result in the incidental take of marine mammals by Level A and Level B harassment in the form of auditory injury or behavioral harassment.

Detailed Description of the Activity

A detailed description of the construction activities for which take is proposed here may be found in the notices of the proposed and final IHAs for the initial authorization (88 FR 9227, February 13, 2023; 88 FR 19927, April 4, 2023). As previously mentioned, this request is for a subset of the activities considered for the initial IHA that would not be completed prior to its expiration. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the previous notice for the initial IHA. The proposed renewal IHA would be effective from April 1, 2024 through March 31, 2025.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which authorization of take is proposed here, including information on abundance, status, distribution, and hearing, may be found in the notice of the proposed IHA for the initial authorization (88 FR 9227, February 13, 2023).

Since the initial IHA was published, NMFS published the final 2022 Alaska and Pacific Stock Assessment Reports (SARs), which describe revised stock structures under the MMPA for humpback whales. In the initial notice of proposed and final IHAs, we explained these proposed changes and that these changes would be adopted when final. Upon finalization of these revised stock structures, we have made appropriate updates, including attribution of take numbers to stock (see Estimated Take).

The revision to humpback whale stock structure modifies the previously MMPA-designated humpback stocks to align more closely with the ESA-designated distinct population segments (DPSs) (Caretta *et al.,* 2023; Young *et al.,* 2023). Specifically, the three existing North Pacific humpback whale stocks (Central North Pacific and Western North Pacific stocks addressed in the Alaska SAR and the California/Oregon/Washington stock addressed in the Pacific SAR) were replaced by five stocks (Western North Pacific, Hawaii, and Mexico-North Pacific stocks addressed in the Alaska SAR and the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks addressed in the Pacific SAR) (Caretta *et al.,* 2023; Young *et al.,* 2023).

In the initial notice of the proposed and final IHA, NMFS assumed that humpbacks in the action area were from the Central North Pacific Stock, Western North Pacific Stock, and CA/OR/WA Stock, and therefor authorized take of humpbacks from these stocks. Based on the revised stock designations, no take of WNP stock whales would occur, and in the proposed renewal IHA humpback whales are now assumed to be members of either the Hawaii stock or the Mexico-North Pacific stock, which corresponds with the takes previously authorized for the Central North Pacific Stock and CA/OR/WA Stocks, respectively. However, based on the work remaining in the renewal IHA, the takes proposed for authorization through this renewal would only be from the Hawaii stock. In southeast Alaska, it is likely that only 2% of humpbacks would be from the Mexico-North Pacific stock, and based on the proportionally reduced take in this renewal, there are no calculated takes of the Mexico-North Pacific stock. Therefor in this renewal IHA, we propose to authorize take only of the Hawaii stock of humpback whale.

NMFS has reviewed the preliminary monitoring data from the initial IHA, recent draft and final Stock Assessment Reports including the updated humpback whale stock structure, and determined that neither this nor any other new information affects which species have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial IHA (88 FR 9227, February 13, 2023).

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which the authorization of take is proposed here may be found in the notice of the proposed IHA for the initial authorization (88 FR 9227, February 13, 2023). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the notices of the proposed and final IHAs for the initial authorization (88 FR 9227, February 13, 2023; 88 FR 19927, April 4, 2023). Specifically, days of operation, area or space within which harassment is likely to occur, and marine mammal occurrence data applicable to this authorization remain unchanged from the initial IHA. Similarly, methods of take, daily take estimates and types of take remain unchanged from the initial IHA. The number of takes proposed for authorization in this renewal are a subset of the initial authorized takes that better represent the amount of activity left to complete. These takes, which reflect the lower number of remaining days of work, are indicated below in table 1. Takes are calculated using the same methodology as the initial IHA, and are just a proportion of the initial takes based on the days of work remaining.

TABLE 1—PROPOSED AMOUNT OF TAKING, BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Species	Stock	Proposed Level A Take	Proposed Level B Take	Percent of stock
Humpback Whale	Hawaii	0	3	<1

TABLE 1—PROPOSED AMOUNT OF TAKING, BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK—Continued

Species	Stock	Proposed Level A Take	Proposed Level B Take	Percent of stock
	Mexico-North Pacific	0	0	0
	Western North Pacific	0	0	0
Killer Whale	Alaska Resident	0	11	<1
	Gulf of Alaska/Aleutian Islands/Bering Sea Transient.	0	3	<1
Dall's Porpoise	Alaska	4	6	<1
Harbor Seal	Prince William Sound	4	18	<1
Steller Sea Lion	Western United States	0	24	<1

Description of Proposed Mitigation, Monitoring and Reporting Measures

The proposed mitigation, monitoring, and reporting measures included as requirements in this authorization are almost identical to those included in the FR notice announcing the issuance of the initial IHA, and the discussion of the least practicable adverse impact included in that document remains accurate (88 FR 19927, April 4, 2023).

The following mitigation, monitoring, and reporting measures are proposed for this renewal:

- The TMC must avoid direct physical interaction with marine mammals during construction activity. If a marine mammal comes within 10-m of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions, as necessary to avoid direct physical interaction;
- Conduct training between construction supervisors and crews and the marine mammal monitoring team and relevant TMC staff prior to the start of all pile driving activity and when new personnel join the work, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood;
- Pile driving activity must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone;
- TMC will establish and implement the shutdown zones. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones typically vary based on the activity type and marine mammal hearing group;
- Monitoring must take place from 30 minutes prior to initiation of construction activity (*i.e.,* pre-start clearance monitoring) through 30 minutes post-completion of construction activity;
- Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead Protected Species Observer (PSO) to determine the shutdown zones clear of marine mammals. Construction may commence when the determination is made;
- If construction is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal;
- TMC must use soft start techniques when impact pile driving. Soft start requires contractors and equipment to slowly approach the work site creating a visual disturbance allowing animals in close proximity to construction activities a chance to leave the area prior to stone resetting or new stone placement. A soft start must be implemented at the start of each day's construction activity and at any time following cessation of activity for a period of 30 minutes or longer;
- The TMC must employ up to four PSOs to monitor the shutdown and Level B harassment zones during pile driving and DTH activities;
- Monitoring will be conducted 30 minutes before, during, and 30 minutes after construction activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from construction activity;
- The TMC must submit a draft report detailing all monitoring within 90 calendar days of the completion of marine mammal monitoring or 60 days prior to the issuance of any subsequent IHA for this project, whichever comes first;
- TMC must conduct hydroacoustic monitoring as specified in the initial IHA and submit a hydroacoustic monitoring report;
- The TMC must prepare and submit final report within 30 days following resolution of comments on the draft report from NMFS;
- The TMC must submit all PSO datasheets and/or raw sighting data (in a separate file from the Final Report referenced immediately above); and
- The TMC must report injured or dead marine mammals.

Comments and Responses

As noted previously, NMFS published a notice of a proposed IHA (88 FR 9227, February 13, 2023) and solicited public comments on both our proposal to issue the initial IHA for Whittier Head of the Bay cruise ship dock project and on the potential for a renewal IHA, should certain requirements be met. During the 30-day public comment period, NMFS received no comments on either the proposal to issue the initial IHA for TMC's construction activities or on the potential for a renewal IHA.

Preliminary Determinations

The proposed renewal request consists of a subset of activities analyzed through the initial authorization described above. In analyzing the effects of the activities for the initial IHA, NMFS determined that TMC's activities would have a negligible impact on the affected species or stocks and that authorized take numbers of each species or stock were small relative to the relevant stocks (*e.g.,* less than one-third the abundance of all stocks). The mitigation measures and monitoring and reporting requirements as described above are identical to the initial IHA.

NMFS has preliminarily concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the

information and analysis contained here and in the referenced documents, NMFS has preliminarily determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) TMC's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action; and (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act

The NMFS Alaska Regional Office issued a Biological Opinion under section 7 of the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) on the issuance of an IHA and potential renewal IHA to TMC under section 101(a)(5)(D) of the MMPA by the NMFS Office of Protected Resources. The Biological Opinion concluded that the action is not likely to jeopardize the continued existence of ESA-listed humpback whales or Steller sea lions.

Proposed Renewal IHA and Request for Public Comment

As a result of these preliminary determinations, NMFS proposes to issue a renewal IHA to TMC for conducting the cruise ship dock construction in Whittier, Alaska, from April 1, 2024 through March 31, 2025, provided the previously described mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed and final initial IHA can be found at *https://www.fisheries.noaa.gov/action/incidental-take-authorization-turnagain-marine-constructions-cruise-dock-construction.* We request comment on our analyses, the proposed renewal IHA, and any other aspect of this notice. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

Dated: February 29, 2024.

Angela Somma,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–04686 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD727]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: Pacific Fishery Management Council (Pacific Council) staff will provide an online briefing on the outcomes of the January 18–19, 2024, meeting of the Ad Hoc Committee of the Whole.

DATES: The online meeting will be held on Friday, March 29, 2024, 3–5 p.m. Pacific time.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kelly Ames, Deputy Director, Pacific Council; telephone: (503) 820–2417.

SUPPLEMENTARY INFORMATION: The Pacific Council created the Ad Hoc Committee of the Whole (COTW), composed of Pacific Council members, to make recommendations on Council operations in light of the Pacific Council's medium and long-term financial status. A report of the COTW, including its recommendations, will be reported to the Pacific Council at its April 9–11, 2024, meeting. Based on these recommendations, the Pacific Council's Executive Director will propose potential changes to Pacific Council operations in line with anticipated budget ceilings for the next three to five years. In this online briefing Pacific Council staff will summarize outcomes of the COTW meeting for Pacific Council advisory bodies and the public to allow informed comment at the April Pacific Council meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 1, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–04748 Filed 3–5–24; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB–2024–0007]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (CFPB) is requesting the Office of Management and Budget's (OMB's) approval for a new information collection titled ''Consumer Complaint Survey.''

DATES: Written comments are encouraged and must be received on or before May 6, 2024 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2024–0007 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Because paper mail in the

Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Consumer Complaint Survey.

OMB Control Number: 3170–00XX.

Type of Review: New information collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 13,200.

Estimated Total Annual Burden Hours: 6,600.

Abstract: The Dodd-Frank Wall Street Reform and Consumer Protection Act charges the CFPB with researching, analyzing, and reporting on topics relating to the CFPB's mission including consumer behavior, consumer awareness, and developments in markets for consumer financial products and services. To improve its understanding of consumers and institutional actors in financial markets, the CFPB makes use of data collected through the complaint process. The CFPB seeks to enhance the utility of these data by better understanding the broader population of consumers who experience issues with their financial products and services.

The CFPB proposes to collect data with two new surveys intended to identify factors that influence a consumer's decision to use the complaint process. The initial pilot survey will focus on consumers who have experienced issues with their credit cards and will include a sample of people who have used the CFPB's complaint process, and another sample of people who experienced similar issues but did not file a complaint with the CFPB. This design (known as a case-control study) will allow us to identify key factors that are associated with submitting regulatory complaints.

The pilot survey will inform a second survey which will focus on a broader range of products and services. The second survey will (to the extent feasible) cover additional products about which consumers can submit complaints to the CFPB including (but not limited to) mortgages, vehicle loans, bank accounts, and debts owed to third-party debt collectors. Both surveys will collect data about factors that may play a role in consumer's decision to submit a complaint. These include information about their use of a given product, the problems they encountered when using a given product, their attitudes and perceptions towards the product and its offeror, as well as demographic information.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CFPB, including whether the information will have practical utility; (b) The accuracy of the CFPB's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2024–04775 Filed 3–5–24; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

[Permit No. NAE–2020–00707]

Notice of Final Federal Agency Action on the Authorization for the Revolution Wind Farm and Revolution Wind Export Cable Project Offshore Rhode Island

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of limitation on claims for judicial review of actions by the U.S. Army Corps of Engineers (USACE).

SUMMARY: USACE announces final agency action on the USACE authorization for the proposed construction and maintenance of the Revolution Wind Farm and Revolution Wind Offshore Export Cable Project (the Revolution Wind Project) offshore Rhode Island. USACE has issued a permit authorizing the construction and maintenance of the Revolution Wind Project under section 10 of the Rivers and Harbors Act of 1899 (RHA) and section 404 of the Clean Water Act (CWA). The Revolution Wind Project is a ''covered project'' under title 41 of the Fixing America's Surface Transportation Act.

DATES: A claim seeking judicial review of the USACE authorization of construction and maintenance of the Revolution Wind Project will be barred unless the claim is filed not later than two years after this notice's publication date. If the Federal law that allows for judicial review of the USACE authorization specifies a shorter time period for filing such a claim, then that shorter time period will apply.

FOR FURTHER INFORMATION CONTACT: Ms. Ruth Brien, Regulatory Project Manager, Regulatory Division, USACE, New England District, 696 Virginia Road, Concord, Massachusetts 01742, (978) 318–8054 or *cenae-r-offshorewind@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that USACE has taken final agency action on its authorization for the proposed Revolution Wind Project by issuing a permit authorizing construction and maintenance of the Project under section 10 of the RHA and section 404 of the CWA. The majority of the authorized work will occur in the Atlantic Ocean within the Bureau of Ocean Energy Management (BOEM) Renewable Energy Lease Area OCS–A–0486, which is approximately 15 nautical miles (nm) southeast of Point Judith, Rhode Island, approximately 13 nm east of Block Island, Rhode Island, and approximately 7.5 nm south of Nomans Land Island National Wildlife Refuge.

The work authorized under the USACE permit includes the following: (1) the installation of up to 65 wind turbine generators (WTGs) and up to 2 offshore substations (OSSs) with associated scour protection, (2) the installation of 155 miles of inter-array cables connecting the WTGs and 9 miles of inter-link cables connecting the OSSs with associated secondary cable protection as needed, and (3) installation of up to 2 export transmission cables with associated secondary cable protection within a 42-

mile-long offshore export cable corridor extending from the lease area north into Rhode Island Sound and Narragansett Bay, making landfall near Quonset Point in North Kingstown, Rhode Island.

The USACE's decision to issue a permit, and the laws under which the action was taken, are described in the Revolution Wind Export Cable Project Final Environmental Impact Statement (FEIS) published on July 21, 2023, in the joint Record of Decision (ROD) issued on August 21, 2023, and in other project records. The FEIS, ROD, and other documents can be viewed and downloaded from the BOEM project website at *https://www.boem.gov/renewable-energy/state-activities/revolution-wind.* The USACE permit can be viewed and downloaded from the USACE website at *https://www.nae.usace.army.mil/Missions/Regulatory/Permits-Issued/Orsted-Revolution-Wind-LLC-Oct-2023/.* By this notice, USACE is advising the public of final agency action subject to 42 U.S.C. 4370m–6(a)(1)(A).

Authority: 42 U.S.C. 4370m–6(a)(1)(A).

John P. Lloyd,

Brigadier General, Commanding.

[FR Doc. 2024–04780 Filed 3–5–24; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF ENERGY

[EERE–2023–BT–DET–0017]

Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1–2022

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of determination.

SUMMARY: The U.S. Department of Energy (DOE) has reviewed ANSI/ASHRAE/IES Standard 90.1–2022: *Energy Standard for Buildings, Except Low-Rise Residential Buildings* (Standard 90.1–2022) and determined the updated edition would improve energy efficiency in commercial buildings. DOE analysis indicates that buildings meeting Standard 90.1–2022, as compared with buildings meeting the previous 2019 edition, would result in national average *site* energy savings of 9.8 percent of commercial building energy consumption. Under the Energy Conservation and Production Act, as amended (ECPA), upon publication of an affirmative determination, each State is required to review the provisions of their commercial building code regarding energy efficiency, and, as necessary, update their codes to meet or exceed Standard 90.1–2022. Additionally, this notice provides guidance on state code review processes and associated certifications.

DATES: Certification statements provided by States shall be submitted by March 6, 2026.

ADDRESSES: A copy of the supporting analysis, as well a link to the Federal docket, is available at: *www.energycodes.gov/development/determinations.*

Certification Statements must be addressed to the Building Technologies Office—Building Energy Codes Program Manager, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, EE–5B, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremiah Williams; U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, EE–5B, Washington, DC 20585; (202) 441–1288; *Jeremy.Williams@ee.doe.gov.*

For legal issues, please contact: Ms. Laura Zuber; U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW, GC–33, Washington, DC 20585; (240) 306–7651; *Laura.Zuber@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Title III of the Energy Conservation and Production Act, as amended (ECPA), establishes requirements for DOE to review consensus-based building energy conservation standards. (42 U.S.C. 6831 *et seq.*) Section 304(b), as amended, of ECPA provides that whenever the ANSI/ASHRAE/IESNA [1] Standard 90.1–1989 (Standard 90.1–1989 or 1989 edition), or any successor to that code, is revised, the Secretary of Energy (Secretary) must make a determination, not later than 12 months after such revision, whether the revised code would improve energy efficiency in commercial buildings, and must publish notice of such determination in the **Federal Register**. 42 U.S.C. 6833(b)(2)(A). If the Secretary makes an affirmative determination, within two years of the publication of the determination, each State is required to certify that it has reviewed and updated the provisions of its commercial building code regarding energy efficiency with respect to the revised or successor code and include in its certification a demonstration that the provisions of its commercial building code, regarding energy efficiency, meet or exceed the revised standard. 42 U.S.C. 6833(b)(2)(B)(i).

ANSI/ASHRAE/IES Standard 90.1–2022 (Standard 90.1–2022 or the ''Standard''), the most recent edition, was published in January 2023, triggering the statutorily required DOE review process. Standard 90.1–2022 is developed under ANSI-approved procedures,[2] a public review and consensus process through which any interested party can participate, and is under continuous maintenance under the purview of an ASHRAE Standing Standard Project Committee (commonly referenced as SSPC 90.1). ASHRAE has an established program for regular publication of addenda, or revisions, including procedures for timely, documented, public review and consensus action on requested changes to Standard 90.1–2022. More information on the consensus process and Standard 90.1–2022 is available at *www.ashrae.org/technical-resources/bookstore/standard-90-1.*

In support of its model energy code determinations, DOE conducts a technical analysis to assess the energy savings impacts associated with the updated code (Standard 90.1–2022). DOE's review under ECPA is technical in nature and helps to inform and advise interested industry stakeholders of the effects of the updated code, as well as states and local governments who ultimately adopt, implement and enforce building codes. Although, DOE is an active participant in the review and update process for Standard 90.1–2022, as directed under ECPA (42 U.S.C. 6836(b)), the Department neither administers nor publishes the model energy codes. Additionally, the directive for states to update their energy efficiency codes based on the updated edition of Standard 90.1–2022 is ultimately rooted in ECPA. DOE's technical analysis serves as basis for DOE's determination and helps inform adopting states who seek to update their codes and comply with ECPA.

DOE's full technical analysis, including assumptions and parameters applied in the analysis, is published as a separate technical support document (TSD) and available for review at *www.energycodes.gov/sites/default/*

[1] ANSI—American National Standards Institute; ASHRAE—American Society of Heating, Refrigerating, and Air-Conditioning Engineers; IES—Illuminating Engineering Society.

[2] See *www.ansi.org/american-national-standards/info-for-standards-developers/standards-developers.*

files/2024-02/Standard_90.1-2022_Final_Determination_TSD.pdf.

DOE publishes a wide range of technical assistance resources supporting building energy codes. This includes additional technical analyses evaluating the impacts of updated building energy codes, such as quantifying energy and environmental benefits, as well as additional resources supporting the adoption and successful implementation of energy codes across states and local governments. New federal assistance is also available supporting state and local adoption and implementation of building energy codes through the Bipartisan Infrastructure Law (Section 40511) and Inflation Reduction Act (Section 50131). Visit *www.energycodes.gov* to learn more about these initiatives and technical assistance resources.

II. Determination Statement

Commercial buildings meeting Standard 90.1–2022 (compared to the previous 2019 edition) are expected to experience the following savings on a weighted national average basis:

- 9.8 percent *site* energy savings
- 9.4 percent *source* energy savings
- 8.9 percent energy *cost* savings
- 9.3 percent carbon emissions savings

DOE concludes that Standard 90.1–2022 will improve energy efficiency in commercial buildings, and, therefore, receives an affirmative determination under Section 304(a) of ECPA.

III. State Certification

Upon publication of this affirmative determination, ECPA requires each State to review and update, as necessary, the provisions of its commercial building energy code to meet or exceed the Standard 90.1–2022 with regard to energy efficiency.[3] 42 U.S.C. 6833(b)(2)(B)(i). This must be completed not later than 2 years from the date the Notice of Determination is published in the **Federal Register**, unless an extension is provided.

State Review & Update

DOE recognizes that some States do not have a State commercial building energy code or have a State code that does not apply to all commercial buildings. States may base their certifications on reasonable actions by units of general-purpose local government. Each such State must review the information obtained from the local governments and gather any additional data and testimony in preparing its own certification.

The applicability of any State revisions to new or existing buildings would be governed by the State building codes. States should be aware that the scope of Standard 90.1–2022 includes high-rise (greater than three stories) multi-family residential buildings, and hotels, motels, and other transient residential building types of any height, as commercial buildings for energy code purposes. Consequently, commercial buildings, for the purposes of certification to DOE, would include high-rise multi-family residential buildings, hotels, motels, and other transient residential building types of any height.

State Certification Statements

Section 304(b) of ECPA, as amended, requires each State to certify to the Secretary of Energy that it has reviewed and updated the provisions of its commercial building energy code regarding energy efficiency to meet or exceed the Standard 90.1–2022. 42 U.S.C. 6833(b). The certification must include a demonstration that the provisions of the State's commercial building energy code regarding energy efficiency meets or exceeds Standard 90.1–2022. If a State intends to certify that its commercial building energy code already meets or exceeds the requirements of Standard 90.1–2022, the State should provide an explanation of the basis for this certification (*e.g.,* Standard 90.1–2022 is incorporated by reference in the State's building code regulations). The chief executive of the State (*e.g.,* the governor), or a designated State official (*e.g.,* director of the State energy office, State code commission, utility commission, or equivalent State agency having primary responsibility for commercial building energy codes), would provide the certification to the Secretary. Such a designated State official would also provide the certifications regarding the codes of units of general purpose local government based on information provided by responsible local officials.

The DOE Building Energy Codes Program tracks and reports State code adoption and certification.[4] Once a State has adopted an updated energy code, DOE strives to provide technical assistance supporting the successful implementation of such codes, including compliance tools, education and training, and support for the updated code. DOE has issued previous guidance on how it intends to respond to technical assistance requests related to implementation resources, such as building energy code compliance software. 79 FR 15112. The DOE Secretary is directed to provide incentive funding to States to implement the requirements of section 304, and to improve and implement State residential and commercial building energy efficiency codes, including increasing and verifying compliance with such codes. *See* 42 U.S.C. 6833(e). The Bipartisan Infrastructure Law (BIL)[5] and Inflation Reduction Act (IRA)[6] also provide substantial assistance—over $1.2 billion in federal funding—supporting the adoption and implementation of updated building energy codes. DOE does not prescribe how each State adopts and enforces its energy codes.

Requests for Extensions

Section 304(c) of ECPA requires that the Secretary permit an extension of the deadline for complying with the certification requirements described previously, if a State can demonstrate that it has made a good faith effort to comply with such requirements and that it has made significant progress toward meeting its certification obligations. (42 U.S.C. 6833(c)) Such demonstrations could include one or both of the following: (1) a plan for response to the requirements stated in Section 304; or (2) a statement that the State has appropriated or requested funds (within State funding procedures) to implement a plan that would respond to the requirements of Section 304 of ECPA. This list is not exhaustive. Requests are to be sent to the address provided in the **ADDRESSES** section or submitted to *BuildingEnergyCodes@ee.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on February 26, 2024, by Jeffrey M. Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been

[3] Standard 90.1.-2022 added prescriptive requirements for onsite energy generation in certain building types and climate zones which is to be achieved through the use of renewable energy systems. This determination excludes these provisions relating to renewable energy systems because they fall outside the scope of DOE's section 6833(2)(B) review. However, related impacts on whole-building energy savings are reported in DOE's technical analysis developed in support of this determination.

[4] Available at *www.energycodes.gov/adoption/states.*

[5] *www.energycodes.gov/RECI.*

[6] *www.energy.gov/scep/technical-assistance-adoption-building-energy-codes.*

authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–04717 Filed 3–5–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection Revision; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice and request for OMB review and comment; correction.

SUMMARY: The Department of Energy (DOE) published in the **Federal Register** on February 21, 2024, a notice of a Proposed Agency Information Collection Revision. DOE's Office of Energy Efficiency and Renewable Energy (EERE) had submitted to the Office of Management and Budget (OMB) for clearance, a proposal for a three-year extension, with changes, of a collection of information under the provisions of the Paperwork Reduction Act of 1995. This document makes a correction to that notice.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the EERE Environmental Questionnaire should be directed to Andrew M. Montano at: *EEREEQComments@ee.doe.gov.* The EERE Environmental Questionnaire also is available for reviewing in the Golden Field Office Public Reading Room at: *www.energy.gov/node/2299401.* If you have difficulty accessing this document, please contact Casey Strickland at (720) 356–1575.

Correction

In the **Federal Register** of February 21, 2024, FR Doc. 2024–03470 (89 FR 13060), under the **FOR FURTHER INFORMATION CONTACT** section, in the first sentence, remove the email address ''*EREEQComments@ee.doe.gov*'' and add in its place ''*EEREEQComments@ee.doe.gov*''.

Signing Authority

This document of the Department of Energy was signed on February 29, 2024, by Matthew Blevins, Director, Environment, Safety and Health Office, Golden Field Office, Office of Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–04742 Filed 3–5–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Electric Vehicle Working Group

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: The Department of Energy hereby publishes a notice of open meeting of the Electric Vehicle Working Group (EVWG). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, April 2, 2024; 9:30 a.m. to 4 p.m. Eastern Time and Wednesday, April 3, 2024; 8:30 a.m. to 2:30 p.m. Eastern Time. Start and end times may change slightly. Please visit *https://driveelectric.gov/ev-working-group* for the most up to date agenda.

ADDRESSES: The meeting will be held for members of the EVWG at the U.S. Department of Transportation 1200 New Jersey Avenue SE, Washington, DC 20590. Members of the public who would like to participate may do so virtually and must register at: *https://driveelectric.gov/ev-working-group.*

FOR FURTHER INFORMATION CONTACT: Dr. Rachael Nealer, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585; email: *evwg@ee.doe.gov;* telephone: (202) 586–3916.

SUPPLEMENTARY INFORMATION:

Background: The Electric Vehicle Working Group (EVWG) was formed by the Joint Office of Energy and Transportation to make recommendations to the Secretaries of Energy and Transportation regarding the development, adoption, and integration of light-, medium-, and heavy-duty electric vehicles (EVs) into the U.S. transportation and energy systems.

Purpose of the Meeting: This is the first in-person meeting of the EVWG.

Tentative Agenda: The meeting will start at 9:30 a.m. Eastern Time on Tuesday, April 2, 2024. The tentative meeting agenda includes: a review and vote of the EVWGs first report, updates from subcommittees, and a series of technical presentations. Meeting materials and a link to registration can be found here: *https://driveelectric.gov/ev-working-group.*

Public Participation: The meeting will be held in-person for members of the EVWG. Members of the public who would like to participate may do so virtually and must register at: *https://driveelectric.gov/ev-working-group.*

Individuals and representatives of organizations who would like to offer comments and suggestions may do so during the public comment portion of the meeting. Approximately 30 minutes will be reserved for public comments near the end of each meeting day. Time allotted per speaker will depend on the number who wish to speak but will not exceed three minutes. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Those wishing to speak during the public comment period should indicate so within their registration.

Those not able to attend the meeting or who have insufficient time to address the committee are invited to send a written statement to Dr. Rachael Nealer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or email: *evwg@ee.doe.gov.*

Minutes: The minutes of the meeting will be available on *https://driveelectric.gov/ev-working-group* or by contacting Dr. Nealer. She may be reached at the above postal address or email address.

Signing Authority: This document of the Department of Energy was signed on February 29, 2024, by David Borak, Deputy Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–04710 Filed 3–5–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Grid Deployment Office (GDO), U.S. Department of Energy (DOE).

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. The proposed collection will be used to accept applications and required supporting materials from applicants as required to receive payments for hydroelectric incentive programs.

DATES: Comments regarding this proposed information collection must be received before on or before April 5, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–4718.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to Madden Sciubba, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, (240) 798–1195 or by email at *hydroelectricincentives@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1910–NEW.

(2) *Information Collection Request Title:* Hydroelectric Incentive Programs.

(3) *Type of Request:* New.

(4) *Purpose:* Grid Deployment Office (GDO) proposes to collect applications and required supporting documents from applicants as required to receive payments for hydroelectric incentive programs (''Section 242'' Hydroelectric Production Incentives, under 42 U.S.C. 15881; ''Section 243'' Hydroelectric Efficiency Improvement Incentives, under 42 U.S.C. 15882; and ''Section 247'' Maintaining and Enhancing Hydroelectricity Incentives, under 42 U.S.C. 15883), to include ongoing reporting requirements to ensure that incentive payments are used for proper purposes.

(5) *Annual Estimated Number of Respondents:* 200.

(6) *Annual Estimated Number of Total Responses:* 200.

(7) *Annual Estimated Number of Burden Hours:* 8,000 hours.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $2,670.

Statutory Authority: 42 U.S.C. 15881–15883.

Signing Authority

This document of the Department of Energy was signed on February 29, 2024, by Maria D. Robinson, Director, Grid Deployment Office. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–04769 Filed 3–5–24; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R08–OAR–2023–0412; FRL–11808–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Implementation Plan for Oil and Natural Gas Well Production Facilities, Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Federal Implementation Plan for Oil and Natural Gas Well Production Facilities, Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota. (EPA ICR Number 2478.04, OMB Control Number 2008–0001) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act.This is a proposed extension of the ICR, which is currently approved through March 31, 2024. Public comments were previously requested via the **Federal Register** on September 13, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before April 5, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–R08–OAR–2023–0412 to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information

collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Adam Eisele, U.S. Environmental Protection Agency, Region 8, Air and Radiation Division, (Mail Code 8ARD–PM), 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6246, email address: *eisele.adam@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through March 31, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on September 13, 2023 during a 60-day comment period (88 FR 62781). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR covers information collection requirements in the final Federal Implementation Plan (FIP) for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota (40 CFR part 49, subpart K, §§ 49.4161 through 49.4168), herein referred to as the FBIR FIP. In general, owners or operators are required to: (1) conduct certain monitoring; (2) keep specific records to be made available at the EPA's request; and (3) to prepare and submit an annual report (40 CFR part 49, subpart K, §§ 49.4166 through 49.4168). These records and reports are necessary for the EPA Administrator (or the Tribal agency if delegated), for example, to: (1) confirm compliance status of stationary sources; (2) identify any stationary sources not subject to the requirements and identify stationary sources subject to the regulations; and (3) ensure that the stationary source control requirements are being achieved. All information submitted to us pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to the agency policies set forth in 40 CFR part 2, subpart B.

Form numbers: None.

Respondents/affected entities: Owners or operators of oil and natural gas well production facilities on the Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota.

Respondent's obligation to respond: Mandatory (42 U.S.C. 7414).

Estimated number of respondents: 9,007 (total).

Frequency of response: Annually.

Total estimated burden: 137,279 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $41,056,708 (per year), which includes $40,772,356 annualized capital and operation and maintenance costs.

Changes in the estimates: There is an average increase of 25,279 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to anticipated industry growth projected to occur over the next 3-year period of this ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2024–04719 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2010–0757; FRL–11806–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Confidential Financial Disclosure Form for Special Government Employees at the US Environmental Protection Agency (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Confidential Financial Disclosure Form for Special Government Employees at the EPA (EPA ICR Number 2260.08, OMB Control Number 2090–0029) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2024. Public comments were previously requested via the **Federal Register** on September 1, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before April 5, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OA–2010–0757, to EPA online using *www.regulations.gov* (our preferred method), by email to *Docket_OMS@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Gina Moore, Office of Inclusive Excellence, Federal Advisory Committee Management and Oversight Division, Mail Code 1601M, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–566–0462, *moore.gina@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on September 1, 2023 during a 60-day comment period (87 FR 18967). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional

information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The purpose of this information collection request is to assist the EPA in selecting federal advisory committee members who will be appointed as Special Government Employees (SGEs), mostly to the EPA's scientific and technical committees. To select SGE members as efficiently and cost effectively as possible, the Agency needs to evaluate potential conflicts of interest before a candidate is hired as an SGE and appointed as a member to a committee.

Agency officials developed the ''Confidential Financial Disclosure Form for Special Government Employees at the U.S. Environmental Protection Agency,'' also referred to as Form 3110–48, for greater inclusion of information to discover any potential conflicts of interest as recommended by the Government Accountability Office.

Form numbers: EPA Form 3110–48.

Respondents/affected entities: Candidates for membership as SGEs on EPA federal advisory committees. SGEs are required to file a confidential financial disclosure report (Form 3110–48) when first appointed to serve on EPA federal advisory committees, and then annually thereafter. Committee members may also be required to update the confidential form before each meeting while they serve as SGEs.

Respondent's obligation to respond: Required to serve as an SGE on an EPA federal advisory committee (5 CFR 2634.903).

Estimated number of respondents: 325 (total).

Frequency of response: When first appointed to serve on an EPA advisory committee and annually thereafter. Committee members may also be required to update the confidential form before each meeting while they serve as SGEs.

Total estimated burden: 325 hours per year (1 hour per respondent). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $88,400 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–04776 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11785–01–OAR]

Renewable Fuel Standard (RFS) Program Compliance; Biogas Regulatory Reform Rule, Notification of Webinar

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of webinar.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a public webinar on the Biogas Regulatory Reform Rule (BRRR) provisions of the Renewable Fuel Standard (RFS) program.

DATES: The webinar will be held on April 4, 2024, from 1:00–4:30 p.m., Eastern Time. Additional information regarding the workshop appears below under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: All attendees must pre-register for the webinar by notifying the contact person listed under **FOR FURTHER INFORMATION CONTACT** by March 28, 2024. Additional information related to the webinar will be posted at: *https://www.epa.gov/renewable-fuel-standard-program/rfs-set-rule-implementation-webinars.* Interested parties should check the website for any updated information.

FOR FURTHER INFORMATION CONTACT: Nick Parsons, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency; telephone number: (734) 214–4479; email address: *RFS-Hearing@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is hosting a public webinar to discuss the implementation of the Biogas Regulatory Reform Rule (BRRR) provisions promulgated as part of the Renewable Fuel Standard (RFS) final rule for 2023–2025 (the ''Set Rule'').[1] These regulatory provisions include registration and reporting, and updated regulatory provisions for the production, distribution, and use of biogas as a renewable fuel.

During the webinar, EPA intends to discuss various aspects of the BRRR program, including:

- The implementation timeline for BRRR.
- An implementation overview of the BRRR program.
- EPA Central Data Exchange (CDX) registration for biogas producers, renewable natural gas (RNG) producers, RNG RIN separators, and performing required associations.
- Alternative measurement protocols.

EPA will post an agenda approximately one week before the webinar at: *https://www.epa.gov/renewable-fuel-standard-program/rfs-set-rule-implementation-webinars.* Interested parties should check this website for any updated information.

If you require the services of an interpreter or special accommodations such as audio description, please pre-register for the webinar and describe your needs by March 28, 2024. EPA may not be able to arrange accommodations without advance notice.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality.

[FR Doc. 2024–04728 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

[1] 88 FR 44468 (July 12, 2023).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0464 and EPA–HQ–OPPT–2023–0601; FRL–11581–02–OCSPP]

Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); 4,4′-Methylene bis(2-chloroaniline) (MBOCA); Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: In the **Federal Register** of December 18, 2023, EPA announced the initiation and solicitation of public comment on the prioritization process for five chemical substances as candidates for designation as High-Priority Substances for risk evaluation under the Toxic Substances Control Act (TSCA) and related implementing regulations. This document extends the comment period for one of the five chemicals: 4,4′-methylene bis(2-chloroaniline) (MBOCA). The comment period is currently scheduled to end on March 18, 2024.

DATES: The comment period at 88 FR 87423 is extended for MBOCA. Comments for MBOCA must be received on or before April 17, 2024.

ADDRESSES: Submit your comments for MBOCA, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0464, through *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional

instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Sarah Au, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–0398; email address: *au.sarah@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION: In response to a stakeholder's request for additional time to review materials and prepare comments for MBOCA, EPA is extending the comment period for MBOCA that was established in the **Federal Register** document of December 18, 2023, at 88 FR 87423 (FRL–11581–01–OCSPP) for 30 days, from March 18, 2024, to April 17, 2024. The comment period for the other four chemicals is not being extended by this **Federal Register** Notice.

In addition, EPA would also like to clarify that the **Federal Register** document of December 18, 2023, included a typographical error for the year associated with the MBOCA docket ID number. The correct docket ID number for MBCOA is EPA–HQ–OPPT–2018–0464.

To submit comments or access the docket, please follow the detailed instructions provided under **ADDRESSES**. If you have questions, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: February 29, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–04720 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11764–01–OA]

Public Meetings of the Clean Air Scientific Advisory Committee (CASAC) Nitrogen Oxides Panel and the Chartered CASAC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office is announcing two public meetings of the Clean Air Scientific Advisory Committee (CASAC) Nitrogen Oxides (NO_X) Panel and the Chartered CASAC. The purpose of the CASAC NO_X Panel meeting is to provide consultative advice on the Integrated Review Plan for the Primary National Ambient Air Quality Standards (NAAQS) for NO_X, Volume 2. The purpose of the Chartered CASAC meeting is to provide advice on the NAAQS review process.

DATES:

Public meetings: The CASAC NO_X Panel will meet on April 16, 2024, from 11 a.m. to 3 p.m. eastern time. The Chartered CASAC will meet on April 25, 2024, from 11 a.m. to 3 p.m. eastern time.

Comments: See the section titled ''Procedures for providing public input'' under **SUPPLEMENTARY INFORMATION** for instructions and deadlines.

ADDRESSES: Both meetings will be conducted virtually. Please refer to the CASAC website at *https://casac.epa.gov* for information on how to attend the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information concerning this notice may contact Mr. Aaron Yeow, Designated Federal Officer (DFO), via telephone at (202) 564–2050, or email at *yeow.aaron@epa.gov.* General information about the CASAC, as well as any updates concerning the meetings announced in this document, can be found on the CASAC website at *https://casac.epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409(d)(2), to review air quality criteria and NAAQS and recommend to the EPA Administrator any new NAAQS and revisions of existing criteria and NAAQS as may be appropriate. As amended, 5 U.S.C., app. Section 109(d)(1) of the Clean Air Act (CAA) requires that EPA carry out a periodic review and revision, as appropriate, of the air quality criteria and the NAAQS for the six ''criteria'' air pollutants, including NO_X. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S. Code 10. The CASAC and CASAC NO_X panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the CASAC NO_X Panel will hold a public meeting to provide consultative advice on the IRP Vol. 2, and the Chartered CASAC will provide advice on the NAAQS review process.

Availability of meeting materials: All meeting materials, including the agendas, will be available on the CASAC web page at *https://casac.epa.gov.*

Procedures for providing public input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the committee's charge or meeting materials. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for the CASAC to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comments should follow the instruction below to submit comments.

Oral statements: In general, individuals or groups requesting an oral presentation at the meeting will be limited to five minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Persons interested in providing oral statements should contact the DFO, in writing (preferably via email) at the contact information noted under **FOR FURTHER INFORMATION CONTACT**, by April 9, 2024, for the April 16, 2024 meeting, and by April 18, 2024, for the April 25, 2024 meeting, to be placed on the list of registered speakers.

Written statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by CASAC members, statements should be submitted to the DFO by April 9, 2024, for consideration at the April 16, 2024 meeting, and by April 18, 2024, for consideration at the April 25, 2024 meeting. Written statements should be supplied to the DFO at the contact information above via email. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should

be aware that their personal contact information if included in any written comments, may be posted to the CASAC website. Copyrighted material will not be posted without the explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact the DFO, at the contact information noted above, preferably at least ten days before the meetings, to give the EPA as much time as possible to process your request.

V. Khanna Johnston,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2024–04648 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11778–01–ORD]

Request for Nominations of Experts to the EPA Office of Research and Development's Human Studies Review Board Advisory Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates with expertise in the areas of toxicology, bioethics, and statistics to be considered for appointment to its Human Studies Review Board (HSRB) Federal advisory committee. Submission of nominations will be made via the HSRB website at: *https://www.epa.gov/osa/human-studies-review-board.*

DATES: Nominations should be submitted by March 29, 2024.

ADDRESSES: Please submit nominations by completing the nomination form provided on the HSRB website at *https://www.epa.gov/osa/human-studies-review-board.*

FOR FURTHER INFORMATION CONTACT: Any member of the public needing additional information regarding this Notice and Request for Nominations may contact Mr. Tom Tracy, Office of Science Advisor, Policy and Engagement, Office of Research and Development, Mail Code B343–01, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711; via phone/voice mail at: (919) 541–4334; or via email at: *tracy.tom@epa.gov.* General information concerning the HSRB can be found at the following website: *https://www.epa.gov/osa/human-studies-review-board.*

SUPPLEMENTARY INFORMATION:

Background

On February 6, 2006, the Agency published a final rule for the protection of human subjects in research (71 FR 6138) that called for creating a new, independent human studies review board (*i.e.,* HSRB). The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. 10 (Pub. L. 92–463). The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) research proposals and protocols that include human subjects; and (2) reports of completed research with human subjects. Typically, the HSRB reviews protocols and completed studies involving pesticide studies, such as worker exposure studies with agricultural handlers applying pesticides in field conditions; janitorial maintenance personnel applying antimicrobial pesticides in commercial settings; and field efficacy studies for skin applied insect repellent products. The HSRB reports to the EPA Administrator through EPA's Human Subjects Research Review Official (HSRRO). General information concerning the HSRB, including its charter, current membership, and activities can be found on the EPA website at *https://www.epa.gov/osa/human-studies-review-board.*

HSRB Membership

HSRB members serve as special government employees or regular government employees. Members are appointed by the EPA Administrator for either two or three year terms with the possibility of reappointment for additional terms, for a maximum of six years of service. The HSRB convenes on average four times a year, with all of the meetings being virtual. The average workload for HSRB members is approximately 20 hours per meeting, including the time spent at the meeting. Responsibilities of HSRB members include reviewing extensive background materials prior to meetings of the Board, preparing draft responses to Agency charge questions, attending Board meetings, participating in the discussion and deliberations at these meetings, drafting assigned sections of meeting reports, and assisting with the finalization of HSRB reports. EPA compensates special government employees for their time and provides reimbursement for travel and other incidental expenses associated with official government business related to the HSRB meetings.

Members of the HSRB are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, each nominee will be asked to submit confidential financial information that fully discloses, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The information provided is strictly confidential and will not be disclosed to the public. Before a candidate is considered further for service on the HSRB, EPA will evaluate each candidate to assess whether there is any conflict of financial interest, appearance of a lack of impartiality, or prior involvement with matters likely to be reviewed by the Board.

Submission of Nominations

To nominate a candidate for consideration or self-nominate, please visit the HSRB website at *https://www.epa.gov/osa/human-studies-review-board* to access and complete the nomination form. Nominations should include a resume or curriculum vitae providing the nominee's educational background, qualifications, leadership positions in national associations or professional societies, relevant research experience and publications along with a short (one page) biography describing how the nominee meets the above criteria and other information that may be helpful in evaluating the nomination, as well as the nominee's current business address, email address, and daytime telephone number. Interested candidates may self-nominate. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups, as well as from a variety of backgrounds (*e.g.,* industry, non-profit organizations, academia, and government).

Evaluation of Nominations

Nominations will be evaluated on the basis of several criteria, including: professional background, expertise, and experience that would contribute to the diversity of perspectives of the committee; interpersonal, oral, and written communication skills and other attributes that would contribute to the HSRB's collaborative process; consensus building skills; absence of any financial conflicts of interest or the appearance of a lack of impartiality, or lack of independence, or bias; and the

availability to participate in meetings and administrative sessions, participate in teleconferences, develop policy recommendations to the Administrator, and prepare recommendations and advice in reports.

Candidates not selected for HSRB membership at this time may be considered for HSRB membership as vacancies arise in the future or for service as consultants to the HSRB.

To help the Agency in evaluating the effectiveness of its outreach efforts, nominees are requested to inform the Agency of how you learned of this opportunity.

Final selection of HSRB members is a discretionary function of the Agency and will be announced as soon as selections are made on the HSRB website at *https://www.epa.gov/osa/human-studies-review-board.*

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2024–04724 Filed 3–5–24; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Thursday, March 14, 2024.

PLACE: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to observe, at least 24 hours in advance, visit *FCA.gov,* select ''Newsroom,'' then select ''Events.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The following matters will be considered:

PORTIONS OPEN TO THE PUBLIC:

- Approval of Minutes for February 8, 2024

PORTIONS CLOSED TO THE PUBLIC:

- Office of Secondary Market Oversight Periodic Report [1]

CONTACT PERSON FOR MORE INFORMATION: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2024–04837 Filed 3–4–24; 11:15 am]

BILLING CODE 6705–01–P

[1] Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201309–001.

Agreement Name: Maersk Line/Hapag-Lloyd Slot Exchange Agreement.

Parties: Hapag Lloyd AG; Maersk Line A/S.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment revises Article 5.3(a) to permit Hapag-Lloyd to load cargo to/from either Cartagena or Manzanillo on Maersk's OC1 service. The parties have requested expedited review.

Proposed Effective Date: 04/14/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22412.

Dated: March 1, 2024.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–04731 Filed 3–5–24; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 21, 2024.

A. Federal Reserve Bank of Minneapolis (Stephanie Weber, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *Timothy J. Hoese, individually, and as beneficiary with voting rights to the Clayton W. Hoese Irrevocable Trust Under Agreement dated June 18, 1981, as modified September 12, 2023, all of Glencoe, Minnesota;* to become a member of the Hoese/Schornack Family Shareholder Group, a group acting in concert, to retain voting shares of Flagship Financial Group, Inc., Eden Prairie, Minnesota, and thereby indirectly retain voting shares of Flagship Bank Minnesota, Wayzata, Minnesota, and Security Bank & Trust Company, Glencoe, Minnesota.

2. *The Fishback-Mitchell FFC Living Trust established August 16, 2023, Amanda T. Mitchell and John T. Fishback, as co-trustees, all of San Francisco, California;* to become members of the Fishback Family Shareholder Group, a group acting in concert, to retain voting shares of Fishback Financial Corporation, and thereby indirectly retain voting shares of First Bank & Trust, both of Brookings, South Dakota.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–04770 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of availability—new common formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of common definitions and reporting formats (Common Formats or formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the availability of *Common Formats for Surveillance—Hospital Version 1.0* for public review and comment.

DATES: *End of initial comment period:* April 5, 2024.

ADDRESSES: The *Common Formats for Surveillance—Hospital Version 1.0* can be accessed electronically at the following website: *https://www.psoppc.org/psoppc_web/publicpages/surveillancecommonformats.*

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to 299b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect and analyze confidential and privileged information regarding the quality and safety of health care delivery that meets the definition of PSWP. Aggregation of these data enables PSOs and others to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act provides for the development of standardized reporting formats using common language and definitions (Common Formats) to ensure that health care quality and patient safety data collected by PSOs and other entities are comparable. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the formats are intended to enhance the reporting of information that is standardized both clinically and electronically.

AHRQ has developed Common Formats for Event Reporting for three settings of care—acute care hospitals, nursing homes, and community pharmacies—as well as for diagnostic safety events across all care settings. AHRQ-listed PSOs are required to collect patient safety work product in a standardized manner to the extent practical and appropriate; this is a requirement the PSO can meet by collecting such information using Common Formats. Additionally, providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the Federal confidentiality and privilege protections of the Patient Safety Act.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ solicit comments from the private and public sectors regarding proposed versions of the Common Formats through the Patient Safety Organization Privacy Protection Center (PSOPPC). After receiving comments, the PSOPPC will solicit review of the formats by its Common Formats Expert Panel. Subsequently, PSOPPC will review this input and provide its feedback to AHRQ who then uses it to refine the Common Formats.

For the Common Formats, it should be noted that AHRQ uses the term ''surveillance'' in this context to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will allow for collection of comparable performance data over time and across populations of patients. These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems.

AHRQ is specifically interested in receiving feedback in order to guide the improvement of the formats. The draft Event Descriptions for the *Common Formats for Surveillance—Hospital Version 1.0* are available at: *https://www.psoppc.org/psoppc_web/publicpages/surveillancecommonformats.* Comments on the *Common Formats for Surveillance—Hospital Version 1.0* can be submitted through: *https://www.psoppc.org/psoppc_web/publicpages/openforcomment.*

Additional information about the Common Formats can be obtained through AHRQ's PSO website: *https://pso.ahrq.gov/common-formats.*

Dated: March 1, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–04767 Filed 3–5–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force (CPSTF)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention, within the Department of Health and Human Services, announces the next meeting of the Community Preventive Services Task Force (CPSTF) on April 17–18, 2024.

DATES: The meeting will be held on Wednesday, April 17, 2024, from 9 a.m. to 5 p.m. EDT, and Thursday, April 18, 2024, from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be available to the public via web conference.

FOR FURTHER INFORMATION CONTACT: Kenya Turner, Office of Science, Office of Scientific Evidence and Recommendations, Community Guide Program; Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H21–10, Atlanta, GA 30329. Telephone: (404) 718–4592; Email: *CPSTF@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Meeting Accessibility: The CPSTF meeting will be shown via web conference.

All meeting attendees must register by April 10, 2024. CDC will email web

conference login information and the agenda to registrants from the *CPSTF@cdc.gov* mailbox approximately two weeks before the meeting start date.

To register for the meeting, individuals should send an email to *CPSTF@cdc.gov* and include the following information: name, title, organization name, organization address, phone, and email.

Public Comment: Individuals who would like to make public comments during the April meeting must state their desire to do so in an email to the *CPSTF@cdc.gov* mailbox no later than April 10, 2024. The request should include name, organizational affiliation, and topic to be addressed. Public comment must be relevant to one of the topics proposed for the meeting. The requestor will receive instructions related to the public comment process for this meeting after the request is received. A public comment period follows the CPSTF's discussion of each systematic review and will be limited to no more than three minutes per person. Public comments may be used to inform task force discussions and will be included in the meeting summary.

Background on the CPSTF: The CPSTF is an independent, nonfederal panel whose members are appointed by the CDC Director. CPSTF members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion, and public health. The CPSTF was convened in 1996 by HHS to identify community preventive programs, services, and policies that increase health and longevity, save lives and dollars, and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the CPSTF. During its meetings, the CPSTF considers the findings of systematic reviews of existing research and practice-based evidence, and issues recommendations. CPSTF recommendations are not mandates for compliance or spending. Instead, they provide information about evidence-based options that decision makers and affected community members can consider when they are determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The CPSTF's recommendations, along with the systematic reviews of the evidence on which they are based, are compiled on the Community Guide website (*www.thecommunityguide.org*).

Matters proposed for discussion: The agenda will consist of deliberation on systematic reviews of literature. Topics proposed for the April 2024 meeting include substance use, public health emergency preparedness and response, oral health, and social determinants of health. Changes regarding the start and end times for each day, and any updates to agenda topics, will be available on the Community Guide website (*www.thecommunityguide.org*) closer to the date of the meeting.

The meeting agenda is subject to change without notice.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–04779 Filed 3–5–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2024–0017]

Human West Nile Virus Vaccine Meeting and Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public teleconference and request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is announcing a meeting and opportunity to comment on a human West Nile virus (WNV) vaccine. The primary purpose of the meeting is to inform critical next steps toward the deployment of a human WNV vaccine.

DATES: The meeting will be held on April 5, 2024, from 8 a.m. to 5 p.m., eastern time.

Written comments must be received on or before April 4, 2024.

ADDRESSES: You may submit written comments, identified by docket number CDC–2024–0017, by either of the following two methods listed below. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Randall Nett, MD, MPH, Centers for Disease Control and Prevention, 3156 Rampart Road, MS P02, Fort Collins, CO 80521.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC–2024–0017]. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. This will be an in-person and virtual meeting with a limited number of available Zoom lines. The in-person gathering will be by invitation only and held at Constitution Center, 400 7th St. SW, Washington, DC.

Accessibility: For information on access or services for individuals with disabilities, or to request accommodations for a disability, please contact Shawna Zuck by email at *wnv.vaccine@cdc.gov,* or by phone at (970) 221–6400, preferably at least 10 days before the meeting to allow as much time as possible to process your request.

FOR FURTHER INFORMATION CONTACT: Randall J. Nett, MD MPH, Chief, Arboviral Diseases Branch, 3156 Rampart Road, MS P02, Fort Collins, CO 80521; telephone number: (970) 221–6400; email address *wnv.vaccine@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: WNV is a disease spread by mosquitoes that continues to cause illness and deaths each year in the United States and other areas of the world. Current mosquito control measures have been unsuccessful at decreasing the number of WNV disease cases. An approved human WNV vaccine could reduce the public health impact of WNV disease.

Purpose: The primary purpose of the meeting and public comment period is to inform critical next steps toward the development of a human WNV vaccine that is approved for use.

Attending the meeting: The meeting will be open to the general public. The meeting agenda and information on how to register for and attend the meeting online will be provided on request. If interested in attending the meeting online, please email *wnv.vaccine@cdc.gov.* This meeting is open to the public, limited only by the number of Zoom lines. The Zoom line will accommodate up to 500 participants and be available on a first come-first serve basis.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or

supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Oral Statements: CDC will allocate 15 minutes for the public to present oral comments during the meeting. Oral statements will be limited to three minutes per person during the public comment period. It is preferred that only one person present a statement on behalf of a group or organization. Persons interested in presenting an oral statement should send an email to *wnv.vaccine@cdc.gov* by 12 p.m., eastern time, on March 29, 2024. A limited number of time slots are available and will be assigned on a first come-first served basis.

Written Public Comment: Written comments will also be accepted per the instructions provided in the addresses section above. Comments should be submitted on or before April 4, 2024.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–04745 Filed 3–5–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3448–N]

Medicare Program; Announcement of the Re-Approval of COLA Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of COLA for re-approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the following specialty and subspecialty areas under CLIA: Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; Diagnostic Immunology, including Syphilis Serology, and General Immunology; Chemistry, including Routine Chemistry, Toxicology, and Endocrinology; Hematology, including routine hematology and coagulation; Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification; Pathology, including Histopathology, Oral Pathology, and Cytology. We have determined that COLA meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and grant COLA deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from March 6, 2024 to March 6, 2030.

FOR FURTHER INFORMATION CONTACT: Jelani Sanaa, (410) 786–1139.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Re-Approval of COLA as an Accreditation Organization

In this notice, we approve COLA as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty and subspecialty areas under CLIA:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, and General Immunology.
- Chemistry, including Routine Chemistry, Toxicology, and Endocrinology.
- Hematology, including routine hematology and coagulation.
- Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification.
- Pathology, including Histopathology, Oral Pathology, and Cytology.

We have examined the initial COLA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for re-approval of an accreditation organization under subpart E of part 493. We have determined that COLA meets or exceeds the applicable CLIA requirements. We have also determined that COLA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant COLA re-approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the submitted specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by COLA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of COLA's Request for Re-Approval as an Accreditation Organization Under CLIA

The following describes the process we used to determine that COLA's accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve COLA as an accreditation program with deeming authority under the CLIA program. COLA formally applied to CMS for re-approval as an accreditation organization under CLIA for the following specialties and subspecialties:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, and General Immunology.

- Chemistry, including Routine Chemistry, Toxicology, and Endocrinology.
- Hematology, including routine hematology and coagulation.
- Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification.
- Pathology, including Histopathology, Oral Pathology, and Cytology.

In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

COLA submitted a description of its mechanisms for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of COLA's individual accreditation requirements with the comparable condition-level requirements. We determined COLA's policies and procedures for oversight of laboratories performing laboratory testing for the submitted CLIA specialties and subspecialties for inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available, are equivalent to those of CLIA. COLA also submitted descriptions of its infrastructure and procedures for monitoring and inspecting laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. We have determined that the requirements of COLA's accreditation program are equal to or more stringent than our requirements of the CLIA regulations.

Our evaluation determined that COLA requirements regarding waived testing are more stringent than the CLIA requirements at § 493.15(e) that require eligible laboratories to follow the manufacturer's instructions for performing tests and obtain a certificate of waiver as outlined in subpart B, Certificate of Waiver. COLA requires the laboratory director to review quality control results for waived tests monthly and also requires that competency be assessed and documented for personnel performing waived testing.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.801 through 493.865. Like CLIA, all of COLA's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. COLA also encourages its accredited laboratories to participate in PT for tests that are waived under CLIA.

C. Subpart J—Facility Administration for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1200 through 493.1299.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspection

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1771 through 493.1780. COLA will continue to conduct biennial onsite inspections. An unannounced inspection would be performed when a complaint, lodged against a laboratory accredited by COLA, indicates that problems may exist within the laboratory that may have a serious or immediate impact on patient care.

G. Subpart R—Enforcement Procedures

We have determined that COLA meets the requirements of subpart R to the extent that such requirements apply to accreditation organizations. COLA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, COLA will deny, suspend, or revoke accreditation in a laboratory accredited by COLA and report that action to CMS within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by COLA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or CMS agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Deeming Authority as an Accreditation Organization

CLIA regulations provide that we may withdraw the approval of an accreditation organization, such as that of COLA, before the end of the effective date of approval in certain circumstances, in accordance with § 493.575. If we determine that COLA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period 30 days following the date of CMS' determination, not to exceed 1 year, in which COLA would be allowed to address any identified issues, pursuant to our rules at § 493.575(b). Should COLA be unable to address the identified issues, CMS may, in accordance with the applicable regulations, revoke COLA's deeming authority under CLIA.

Should circumstances result in our withdrawal of COLA's re-approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

The information collection requirements associated with the accreditation process for clinical laboratories under the CLIA program are currently the Office of Management and Budget (OMB)-approved under OMB control number 0938–0686 and expires May 31, 2025. Additionally, this notice does not impose any new or revised information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, it does not need to be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–04674 Filed 3–5–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.''

DATES: Either electronic or written comments on the collection of information must be submitted by May 6, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0021 for ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types

OMB Control Number 0910–0744—Revision

This information collection supports food safety projects administered by FDA. The FDA's National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods, released in 2000, 2004, and 2009.[1] [2] [3] Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types.[4]

Using this 10-year survey as a foundation, FDA initiated a new study in full-service and fast-food restaurants. This study will include data collections completed in 2013–2014 and 2017–2018. An additional collection planned for 2021–2022 was halted due to the COVID–19 pandemic; however, an additional data collection is planned for 2023–2025 (the subject of this information collection request extension). Three data collections are necessary to trend the data.

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Full-Service Restaurants	A restaurant where customers place their orders at their tables, are served their meals at the tables, receive the services of the wait staff, and pay at the end of the meals.
Fast-Food Restaurants	A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast, casual restaurants.

Retail Food Stores	Supermarkets and grocery stores that have a deli department/operation as described as follows:
	• Deli department/operation—Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared onsite or received from a commissary in bulk containers, portioned, and displayed. Parts of deli operations may include:
	  • Salad bars, pizza stations, and other food bars managed by the deli department manager.
	  • Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager.
	Data will also be collected in the following areas of a supermarket or grocery store, if present:
	• Seafood department/operation—Areas in a retail food store where seafood is cut, prepared, stored, or displayed for sale to the consumer. In retail food stores where the seafood department is combined with another department (e.g., meat), the data collector will only assess the procedures and practices associated with the processing of seafood.
	• Produce department/operation—Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are managed by the produce manager.

The results of this study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
- Provide technical assistance to State, local, tribal, and territorial regulatory professionals;
- Identify FDA retail work plan priorities; and
- Inform FDA resource allocation to enhance retail food safety nationwide.

The objectives of this study are to:

[1] FDA, ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).'' Available at *https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf.*

[2] FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at *https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf.*

[3] FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at *https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm.*

[4] FDA National Retail Food Team, ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at *https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm.*

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in restaurants within the United States;
- Determine the extent to which Food Safety Management Systems and the presence of a Certified Food Protection Manager impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and
- Determine whether the occurrence of foodborne illness risk factors food safety behaviors/practices in delis differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (*e.g.,* restaurants that are part of an operation with two or more units).

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The ''FDA Food Code'' contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation.[5] The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Retail Food Specialists (Specialists) who serve as the data collectors for the study. A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1—''Establishment Information''; Section 2—''Regulatory Authority Information''; and Section 3—''Foodborne Illness Risk Factor and Food Safety Management System Assessment.'' The information in Section 1 ''Establishment Information'' of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions. The information in Section 2 ''Regulatory Authority Information'' is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment.

Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee handwashing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking followup questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee handwashing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: establishment name, street address, city, State, ZIP Code, county, industry segment, and facility type. The establishment-identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected.

The burden associated with the completion of Sections 1 and 3 of Form FDA 3967 is specific to the persons in charge of the selected facilities. The burden includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. This burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study. FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Fast-Food Restaurants—Completion of Sections 1 and 3	400	1	400	1.36	544
Full-Service Restaurants—Completion of Sections 1 and 3	400	1	400	1.73	692
Fast-Food and Full-Service Restaurants—Completion of Section 2	800	1	800	0.5 (30 minutes)	400
Retail Food Stores—Completion of Form FDA 3967, Sections 1 and 3	400	1	400	3	1,200
Retail Food Stores—Completion of Form FDA 3967, Section 2	400	1	400	0.5 (30 minutes)	200
Entry Refusals—All Facility Types	24	1	24	0.08 (5 minutes)	2
Total					3,038

[1] There are no capital costs of operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. On our own initiative, however, and for efficiency of Agency operations, we are revising the information collection to include and consolidate related information collection found in 0910–0799. Therefore, our estimated burden for the information collection reflects an increase of 1,401 total burden hours and a corresponding increase of 808 total annual responses.

[5] FDA, ''FDA Food Code.'' Available at *https://www.fda.gov/FoodCode.*

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04722 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 5, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0001. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for FDA Approval To Market a New Drug—21 CFR Part 314

OMB Control Number 0910–0001—Revision

This information collection supports implementation of statutory and regulatory authorities that govern new drugs. Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. We have issued regulations in part 314 (21 CFR part 314) that establish procedures and requirements for applications submitted in accordance with section 505 of the FD&C Act. The regulations in subpart A (§§ 314.1 through 314.3) set forth general provisions, while regulations in subparts B and C (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports (PMRs). Respondents to the information collection are sponsors of these applications.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. The information collection includes provisions established through our Agency user fee programs, most recently authorized under the FDA User Fee Reauthorization Act of 2022. These provisions pertain to performance goals, expedited programs, review transparency, communications with FDA, dispute resolution, drug safety enhancements, and the allocation of Agency resources to align with these program objectives as agreed to with our stakeholders and set forth in our ''User Fee Performance Goals for Fiscal Years 2023–2027'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about specific FDA user fee programs.

Included among the provisions in subpart G (§§ 314.410 through 314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates, guidance, forms, and resources available from our website at *https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.* We have developed Form FDA 3938 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. We are revising Form FDA 3898 and the accompanying instructions to allow for multiple selections of submission types and to clarify the number of digits to be entered for the holder and establishment registration numbers.

In accordance with § 314.445, we also develop Agency guidance documents to assist respondents in complying with provisions in part 314. These guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illnesses.

Information collection and associated burden for the submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of certain new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements, animal studies of safety and efficacy to establish likely clinical benefit in humans and upon approval of the drug product, additional requirements and/or restrictions to ensure safe use of the product. Additional PMRs, safety reporting, and promotional material as well as requirements for withdrawal of these human drug applications, and FDA termination of requirements for these human drug applications are included in §§ 314.620 through 314.650. The estimated burden for these human drug applications is included in the reported submissions and burden under general human drug applications, § 314.50, and other specific regulations in the table for human drug application requirements in general.

Finally, we are also revising the collection to include the submission of information pursuant to the CREATES Act (enacted as part of the Further Consolidated Appropriations Act of 2020 (21 U.S.C. 355–1(1) and 355–2)). Under the CREATES Act, developers of potential drug and biological products are enabled to use the CREATES pathway to obtain samples of brand products that are needed to support their applications. Relevant products include those submitted in generic drug applications under section 505(j) of the FD&C Act and NDAs submitted under

section 505(b)(2) of the FD&C Act, and biosimilar products submitted under section 351(k) of the Public Health Service Act as amended by the Biologics Price Competition and Innovation Act of 2009. One of the requirements for using the CREATES pathway for products that are subject to a Risk Evaluation and Mitigation Strategy with elements to assure safe use is to obtain a Covered Product Authorization (CPA) from FDA (21 U.S.C. 355–2(b)(2)). Included in our estimated burden is effort we attribute to information collection activities associated with CPAs.

To assist respondents to the information collection we have developed the following forms:

- Form FDA 356h (and instructions): Application to Market a New or Abbreviated New Drug or Biologic for Human Use
- Form FDA 2252 (and instructions): Transmittal of Annual Reports for Drugs and Biologics for Human Use (§ 314.81)
- Form FDA 2253 (and instructions): Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use
- Forms FDA 3331/3331a (and instructions): Field Alert Reports
- Form FDA 3542 (and instructions): Patent Information Submitted Upon and After Approval of an NDA or Supplement
- FDA 3542a (and instructions): Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement
- Revised Form FDA 3938 (and revised instruction): DMF submission
- Form FDA 3988 (and instruction): Transmittal of post marketing requirements (PMR)/postmarketing commitments (PMC) submissions for Drugs and Biologics
- Form FDA 3989 (and instruction): Transmittal of PMR/PMC Annual Status Report Information

Individuals requesting printed forms are instructed to contact the FDA Forms Manager by email at *formsmanager@OC.FDA.GOV*. Certain fees may be applicable.

Information collection pertaining to hearings and other administrative proceedings covered in 21 CFR subpart E are approved under OMB Control Number 0910–0191. Unless otherwise noted, information collection pertaining to postmarket safety reporting and associated recordkeeping is approved under OMB Control Numbers 0910–0230, and 0910–0291.

Respondents to the information collection are pharmaceutical industry entities who contribute to the preparation and marketing of pharmaceutical products regulated by the FDA.

In the **Federal Register** of September 28, 2023 (88 FR 66853), we published a notice inviting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart B					
314.50(a)–(l)—Content and format of a 505(b)(1) or 505(b)(2) application ..	85	1.42	121	1,921	232,441
314.50(i)(1)—Patent certifications: Form FDA 3542	170	6.55	1,113	10	11,130
314.50(i)(1)—Patent certifications: Form FDA 3542a	1	1	1	15	15
314.50(i)(6) Amended patent certifications	73	4.33	316	2	632
314.52(a), (b), and (e)—NDAs—Notice of noninfringement of patent certification.	15	3	45	15	675
314.52(c)—Noninfringement of patent certification notice content	22	3	66	0.33 (20 minutes)	22
314.53(f)(1)—Correction of patent information errors by persons other than the NDA holder.	7	1.14	8	10	80
314.53(f)(2)—Correction of patent information errors by the NDA holder	8	1.13	9	1	9
314.60—Amendments to unapproved NDA, supplement or resubmission	269	7.22	1,942	80	155,360
314.60(f)—Patent certifications for unapproved applications	6	1	6	2	12
314.65—Withdrawal of unapproved applications	20	1.05	21	2	42
314.70 and 314.71—Supplements and other changes to approved application.	501	5.13	2,570	150	385,500
314.72—Changes of ownership of NDAs	73	1.67	122	2	244
314.81—Other PMR 314.81(b)(1) [3331 and 3331a field alert reports and follow-ups].	532	18.5	9,834	8	78,672
314.81(b)(2)—[Form FDA 2252]—Annual reports	692	4.46	3,090	40	123,600
314.81(b)(2)—[Form FDA 2253]—Promotional labeling	310	121	37,508	2	75,016
314.81(b)(2)(vii) Form FDA 3988—PMR/PMC	737	0.87	642	24	15,408
314.81(b)(2)(vii) Form FDA 3989—PMR/PMC Annual Status Report for Drugs and Biologics.	737	0.29	216	24	5,184
Subpart C					
314.93—Suitability Petitions	16	1.31	21	24	504
314.94(a) and (d)—ANDA content	213	4.02	857	480	411,360
314.94(a)(12)(viii) Amended patent certifications before approval of ANDA	153	1	153	2	306
314.95(c)—Noninfringement of patents (ANDAs)	209	3	627	16	10,032
314.96(a)(1)—Amendments to unapproved ANDAs	514	26.55	13,647	80	1,091,760
314.96(c) Amendment for pharmaceutical equivalent to a listed drug other than reference listed drug.	1	1	1	300	300
314.96(d)—Patent certification requirements	100	1	100	2	200
314.97—Supplements and other changes to ANDAs	343	17.57	6,027	80	482,160
314.97(b) Supplements to ANDA for pharmaceutical equivalent to a listed drug other than RLD.	1	1	1	300	300
314.99(a)—ANDA Applicants: Withdrawal of unapproved ANDAs	58	2.41	140	2	280
314.99(a)—ANDA Transfer of ownership	137	1.24	170	2	340
Subpart D					
314.101(a)—NDA or ANDA filing over protest	1	1	1	0.5 (30 minutes)	0.5

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.107(e)—notification of court actions or written consent to approval	54	1.98	107	0.5 (30 minutes)	53.5
Subparts G, H, and I					
314.420—Drug Master Files—original Form FDA 3938	491	2.05	1,005	61	61,305
DMF Amendments—Technical	1,335	18.71	24,979	8	199,832
DMF Amendments—REMS	2	1	2	8	16
DM Amendments—administrative	1,024	9.67	6,851	6	41,106
DMFs—Annual reports	1,836	6.04	11,097	4	44,388
314.550—Promotional material and subpart H applications [2]	69	5.84	403	120	48,360
CPA Requests for NDA/Biologics License Application Products	1	1	1	5	5
Total					3,476,650

[1] Total burden hours have been rounded.
[2] We have included burden attendant to subpart H applications activity in our estimate of burden associated with § 314.50.

Our estimated burden for the information collection reflects an overall decrease of 642,293.5 hours. The reporting period for this information collection renewal includes the 3 years of the COVID–19 pandemic. We attribute this adjustment to a decrease in the number of submissions received during the public health emergency. We anticipate that the numbers of submissions to FDA will return to pre-pandemic levels as economic activity recovers. We also attribute a portion of the burden adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04715 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2390]

Notice of the Denial of a Hearing Request Regarding a Proposal To Refuse To Approve a Supplemental New Drug Application for HETLIOZ (Tasimelteon)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the decision to deny a request for a hearing regarding the proposal of the Center for Drug Evaluation and Research (CDER) to refuse to approve the supplemental new drug application (sNDA) 205677–004, submitted by Vanda Pharmaceuticals, Inc. (Vanda), for HETLIOZ (tasimelteon) capsules, 20 milligrams (mg), for the treatment of jet lag disorder. The decision, which also refuses approval of sNDA 205677–004, is available in the docket identified by the number in the heading of this document.

DATES: The decision was published in the docket on March 1, 2024.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2014, FDA approved new drug application (NDA) 205677 for HETLIOZ (tasimelteon) for treatment of non-24-hour sleep-wake disorder, a circadian-rhythm disorder that disproportionately afflicts individuals who are totally blind. On October 16, 2018, Vanda submitted the supplemental NDA (sNDA) that is the subject at issue here: sNDA 205677–004 for HETLIOZ (tasimelteon) capsules, 20 mg, proposing to add a new indication for the treatment of jet lag disorder. On December 1, 2020, FDA approved NDA 214517 for HETLIOZ (tasimelteon) suspension for the treatment of nighttime sleep disturbances in pediatric patients with Smith-Magenis Syndrome, a rare genetic neurodevelopment disorder.

On July 1, 2022, Vanda requested an opportunity for a hearing under 21 CFR 314.110(b)(3) on whether there are grounds under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) for denying approval of sNDA 205677–004 for the treatment of jet lag disorder. On August 29, 2022, CDER notified Vanda by registered mail, providing it with a notice of opportunity for a hearing (NOOH) on a proposal to refuse to approve sNDA 205677–004. The NOOH was subsequently published in the **Federal Register** of October 11, 2022 (87 FR 61337).

On November 10, 2022, Vanda filed a notice of participation and requested a hearing and, on December 12, 2022, submitted information, data, and analyses in support of that request. On June 12, 2023, CDER submitted a proposed order denying Vanda's request for a hearing and refusing to approve the sNDA. On August 11, 2023, Vanda responded to CDER's proposed order. On September 8, 2023, CDER submitted a reply, which included a revised proposed order.

After considering the parties' submissions, on March 1, 2024, FDA issued a decision denying Vanda's request for a hearing on CDER's proposal to refuse approval and refusing to approve sNDA 205677–004.

II. Electronic Access

Persons with access to the internet may obtain the final decision at *https://www.regulations.gov/docket/FDA-2022-N-2390*. The final decision and other documents pertaining to the refusal to approve HETLIOZ (sNDA 205677–004) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: March 1, 2024.

Namandjé N. Bumpus,

Principal Deputy Commissioner.

[FR Doc. 2024–04735 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2781]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 5, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0695. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data To Support Drug Product Communications as Used by the Food and Drug Administration

OMB Control Number 0910–0695—Extension

This information collection supports Agency outreach and other proactive communication efforts. Evaluating communication messages and supporting materials in advance of a communication campaign provides an important role in improving FDA communications as they allow for an indepth understanding of individuals knowledge, attitudes, beliefs, motivations, feelings, and behaviors. Such evaluations are critical in helping FDA develop public health communications that meet the needs and desires of its many diverse target audiences.

We intend to use the following methods with general public health consumers and healthcare professionals in our efforts: individual indepth interviews, focus group discussions, intercept interviews, self-administered surveys, and gatekeeper surveys, all on a voluntary basis. The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative and/or quantitative research tools, have two major purposes: (1) to obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns and (2) to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. We will use these methods to test and refine our ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

We will use this qualitative and/or quantitative research to test messages about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions and about use of drug products and related materials, including but not limited to: (1) direct-to-consumer prescription drug promotion; (2) labeling and information about prescription and over-the-counter drugs; (3) patient medication guides; (4) safety and risk communications; (5) online sale of medical products; and (6) consumer and professional education. Annually, we project about 75 communication studies using the variety of research methods listed in this document. FDA is requesting an extension of these burden hours so as not to restrict its ability to gather information on public opinion for its regulatory and communications programs.

In the **Federal Register** of September 29, 2023 (88 FR 67311), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	45,000	1	45,000	0.75 (45 minutes)	33,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have increased our estimated burden to allow for additional individual collections under the approved generic clearance. For more detailed information regarding individual collections conducted under the currently approved generic clearance, please see our supporting statement at *https://www.reginfog.gov.* We believe that increasing the frequency of individual collections will improve our ability to timely deliver important drug product communications to specific populations, including vulnerable populations that include patients with certain medical conditions.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04716 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5280]

Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' The guidance focuses on frequently asked questions about the new dietary ingredient notification submission and review process. The guidance is intended to help manufacturers and distributors of new dietary ingredients and dietary supplements prepare and submit new dietary ingredient notifications to FDA.

DATES: The announcement of the guidance is published in the **Federal Register** on March 6, 2024

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–5280 for ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Dietary Supplement Programs, HFS–810, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740; or Deirdre Jurand, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of July 5, 2011 (76 FR 39111), we announced the availability of a draft guidance for industry entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues'' and gave interested parties an opportunity to submit comments by October 3, 2011. Among other topics, the July 2011 draft guidance discussed FDA's views and recommendations on when an ingredient intended for use in a dietary supplement is a new dietary ingredient (NDI), when the requirement to submit a new dietary ingredient notification (NDIN) to FDA applies, the types of data and information that manufacturers and distributors should consider when they

evaluate the safety of a dietary supplement containing an NDI, what to include in an NDIN (including recommendations about identity and safety information), and the procedures for submitting an NDIN. We received significant comments and decided to issue a revised draft guidance.

In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry'' to replace the July 2011 draft guidance. In the notice of availability, we gave interested parties an opportunity to submit comments on the 2016 revised draft guidance by October 11, 2016. On October 4, 2016, we extended the comment period for the revised draft guidance to December 12, 2016 (81 FR 68434). We received numerous comments on the 2016 revised draft guidance, including requests for FDA to separate the 2016 revised draft guidance into discrete sections for ease of use. The final guidance whose availability we are announcing through this document reflects that approach. The guidance finalizes Section V of the 2016 revised draft guidance, ''NDI Notification Procedures and Timeframes,'' as well as several related questions from other sections. Changes since the revised draft guidance include providing the following: additional clarity on the procedures for preparing and submitting an NDIN; technical updates related to recent changes to our online submission portal for NDINs; and more information about communications with FDA during the NDIN review process. In addition, we made editorial changes to improve clarity. We understand the importance of finalizing other parts of the 2016 revised draft guidance, and we plan to finalize other individual sections as we complete our review and analysis of those sections.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 190.6 and found in the guidance have been approved under OMB control number 0910–0330.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04718 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: CDR George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, by mail at 5600 Fishers Lane, 8W25A, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of Health and Human Services (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. This responsibility has been delegated to the Director, Division of Injury Compensation Programs. This figure is calculated using the most recent Medical Expenditure Panel Survey—Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation Employer Health Benefits Survey.

In 2023, the Medical Expenditure Panel Survey—Insurance Component, available at *www.meps.ahrq.gov,* published the annual 2022 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was $7,590. This figure is divided by 12 to determine the cost per month of $632.50. The $632.50 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at *www.kff.org.* The increase from 2022 to 2023 was 7 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is $676.78.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is $676.78 per month. In accordance with section 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on February 23, 2024.

Suma Nair,

Associate Administrator, Health System Bureau.

[FR Doc. 2024–04734 Filed 3–5–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of

which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: May 15–16, 2024.

Open: May 15, 2024, 10:00 a.m. to 5:30 p.m.

Agenda: Report by the Director, NINDS; Report by the Acting Director, Division of Extramural Activities; and Administrative and Program Developments.

Open session will be videocast from this link: https://videocast.nih.gov/.

Closed: May 16, 2024, 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6001 Executive Boulevard, Room 1131, Rockville, Maryland 20852 (Hybrid).

Contact Person: David Owens, Ph.D., Director of Extramural Activities (Acting), National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, (301) 496–9248, *owensd@ninds.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: March 1, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04761 Filed 3–5–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; Mentored Clinical Scientist Research Career Development Award (K08/K23).

Date: April 4, 2024.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817.

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817, 240–276–5864, *jennifer.schiltz@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 1, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04762 Filed 3–5–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomaterials, Tissue Engineering, and Drug Delivery.

Date: March 27, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jingwu Xie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8625, *jingwu.xie@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Chemistry, Biochemistry and Biophysics A.

Date: March 27–28, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–4390, *shan.wang@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Biology.

Date: March 27, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Charles Morrow, Ph.D., MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–408–9850, *morrowcs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Applied Immunology and Vaccine Development.

Date: March 27–28, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867–5309, *jiragedb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Auditory, Visual and Cognitive Neuroscience.

Date: March 27, 2024.
Time: 11:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Alena Valeryevna Savonenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J, Bethesda, MD 20892, (301) 594–3444, *savonenkoa2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–23–016: Consortium Organization and Data Collaboration Center (CODCC) for the Human Virome Program (HVP) (U24 Clinical Trial Not Allowed).
Date: March 27, 2024.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Kenneth M. Izumi, Ph.D., Scientific Review Officer, NIH Center for Scientific Review, 6701 Rockledge Drive, MSC 7808, Bethesda, MD 20892, 301–496–6980, *izumikm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Clinical Care and Health Interventions.
Date: March 28, 2024.
Time: 10:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1003–L, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA/REAP: Respiratory, Cardiac and Circulatory Sciences.
Date: March 28, 2024.
Time: 2:00 p.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Kirk E. Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, (301) 867–5309, *dineleyke@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA: HEAL Initiative: Understanding Individual Differences in Human Pain Conditions.
Date: March 28, 2024.
Time: 2:30 p.m. to 7:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1003–L, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 1, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04764 Filed 3–5–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; ESTEEMED Research Education Experiences (R25) Review.
Date: June 10, 2024.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Democracy II, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).
Contact Person: John K Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959, Bethesda, MD 20892, (301) 451–3398, *john.hayes@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: March 1, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04763 Filed 3–5–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Clinical Care and Health Interventions and HIV/AIDS.
Date: March 29, 2024.
Time: 10:00 a.m. to 1:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Shivakumar V. Chittari, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–408–9098, *chittari.shivakumar@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biodata Management and Systems Modeling.
Date: March 29, 2024.
Time: 11:00 a.m. to 8:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Vinod Charles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, 301–435–0902, *charlesvi@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Radiation Therapeutics and Biology.
Date: March 29, 2024.
Time: 11:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–905–8294, *rahman-sesay@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: HIV Clinical Care and Health Interventions.

Date: March 29, 2024.

Time: 1:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shivakumar V. Chittari, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–408–9098, *chittari.shivakumar@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 29, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04685 Filed 3–5–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0182]

National Merchant Marine Personnel Advisory Committee; March 2024 Meetings

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meetings.

SUMMARY: The National Merchant Marine Personnel Advisory Committee (Committee) will conduct a series of meetings over two days in Edmonds, WA to discuss issues relating to personnel in the United States Merchant Marine including the training, qualifications, certification, documentation, and fitness of mariners.

DATES:

Meetings: The National Merchant Marine Personnel Advisory Committee is scheduled to meet on Tuesday, March 26, 2024, from 9 a.m. until 4:30 p.m. Pacific daylight time (PDT) and Wednesday, March 27, 2024, from 9 a.m. until 4:30 p.m. (PDT). The Committee meeting on Tuesday, March 26, 2024, will include periods during which the Committee will break into subcommittees. These meetings may adjourn early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meeting, submit your written comments no later than March 18, 2024.

ADDRESSES: The meetings will be held at Compass Courses, additional information about the facility can be found at: *https://compasscourses.com.*

The National Merchant Marine Personnel Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please email Mrs. Megan Johns Henry at *megan.c.johns@uscg.mil* or call at (202) 372–1255 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meetings as time permits, but if you want Committee members to review your comment before the meeting, please submit them no later than March 18, 2024. We are particularly interested in comments on the topics in the ''Agenda'' section below. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2024–0182 in the search box and click ''Search''. Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material using *https://www.regulations.gov,* email the individual in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. You must include the docket number USCG–2024–0182. Comments received will be posted without alteration at *https://www.regulations.gov,* including any personal information provided. You may wish to review the Privacy and Security Notice, found via link on the homepage *https://www.regulations.gov.* For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). If you encounter technical difficulties with comment submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Docket Search: Documents mentioned in this notice as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign-up for email alerts, you will be notified when comments are posted.

FOR FURTHER INFORMATION CONTACT: Mrs. Megan Johns Henry, Alternate Designated Federal Officer of the National Merchant Marine Personnel Advisory Committee, telephone (202) 372–1255, or email *megan.c.johns@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of these meetings is in compliance with the *Federal Advisory Committee Act* (Pub. L. 117–286, 5 U.S.C. ch. 10). The National Merchant Marine Personnel Advisory Committee is authorized by section 601 of the *Frank LoBiondo Act of 2018* and is codified in 46 U.S.C. 15103. The Committee operates under the provisions of the *Federal Advisory Committee Act* and 46 U.S.C. 15109. The National Merchant Marine Personnel Advisory Committee provides advice and recommendations to the Secretary of Homeland Security through the Commandant of the United States Guard on matters relating to personnel in the United States Merchant Marine including the training, qualifications, certification, documentation, and fitness of mariners.

Agenda: The National Merchant Marine Personnel Advisory Committee will meet on Tuesday, March 26, 2024 and Wednesday, March 27, 2024, to review, discuss, deliberate, and formulate recommendations, as appropriate on the following topics:

Day 1

The agenda for the March 26, 2024 meeting is as follows:

(1) The full Committee will meet briefly to discuss subcommittees' business and task statements, which are listed under paragraph (11) under Day 2 below.

(2) During the morning session of the meeting, subcommittees will separately address and work on the following task statements, which are available for viewing at *https://homeport.uscg.mil/missions/federal-advisory-committees/national-merchant-marine-personnel-advisory-committee-(nmerpac)/task-statements:*

(a) Task Statement 21–5, Review of Merchant Mariner Rating and Officer Endorsement Job Task Analyses;

(b) Task Statement 21–4, STCW Convention and STCW Code Review; and

(c) Task Statement 21–2, Communication Between External Stakeholders and the Mariner Credentialing Program.

(3) During the afternoon session of the meeting, subcommittees will separately address and work on the following task statements, which are available for viewing at *https://homeport.uscg.mil/missions/federal-advisory-committees/national-merchant-marine-personnel-advisory-committee-(nmerpac)/task-statements:*

(a) Task Statement 21–5, Review of Merchant Mariner Rating and Officer Endorsement Job Task Analyses;

(b) Task Statement 21–4, STCW Convention and STCW Code Review; and

(c) Task Statement 22–2, Alternative Methods for Meeting STCW Training Requirements at the Operational Level.

(4) Report of subcommittees. At end of the day, the Chair or Co-Chairs of the subcommittees will report to the full Committee on what was accomplished. The full Committee will not take action on this date and the Chair or Co-Chairs of the subcommittees will present a full report to the Committee on Day 2 of the meeting.

(5) Adjournment of meeting.

Day 2

The agenda for the March 27, 2024 meeting is as follows:

(1) Introduction.

(2) Designated Federal Officer and U.S. Coast Guard Leadership remarks.

(3) Roll call of Committee members and determination of a quorum.

(4) Adoption of the agenda.

(5) Acceptance of Minutes from Committee Meeting 6 (December 12, 2023).

(6) Introduction of new task.

(7) Homeport demonstration.

(8) Office of Merchant Mariner Credentialing update presentation.

(9) Public comment period.

(10) National Maritime Center update presentation.

(11) Reports from the subcommittee Chair or Co-Chairs.

The Committee will review the information presented on the following Task Statements and deliberate on any recommendations presented by the subcommittees, recommendations may be approved and completed tasks may be closed. Official action on these topics may be taken:

(a) Task Statement 21–1, Review of IMO Model Courses Being Validated by the IMO HTW Subcommittee;

(b) Task Statement 21–2, Communication Between External Stakeholders and the Mariner Credentialing Program, including amendment Task Statement 21–2A, Reviewing Assessments in NVICS for STCW;

(c) Task Statement 21–3, Military Education, Training, and Assessment for STCW and National Mariner Endorsements;

(d) Task Statement 21–4, STCW Convention and Code Review;

(e) Task Statement 21–5, Review of Merchant Mariner Rating and Officer Endorsement Job Task Analyses;

(f) Task Statement 21–6, Sea Service for Merchant Mariner Credential Endorsements;

(g) Task Statement 21–9, Sexual Harassment and Sexual Assault-Prevention and Culture Change in the Merchant Marine;

(h) Task Statement 22–1, Propulsion Power Limits;

(i) Task Statement 22–2, Alternative Methods for Meeting STCW Training Requirements at the Operational Level;

(j) Task Statement 23–2, Critical Skills for Navigation Using Nautical Charts and Training and Assessments of Skills Using Electronic Navigational Charts; and

(k) Task Statement 23–3, Critical Skills for Radar Navigation and Collision Avoidance and Training and Assessment of Skills Using Radar and Automatic Radar Plotting Aids (ARPA).

(12) Closing remarks.

(13) Adjournment of meeting.

A copy of all meeting documentation will be available at *https://homeport.uscg.mil/missions/federal-advisory-committees/national-merchant-marine-personnel-advisory-committee-(nmerpac)* by March 11, 2024. Alternatively, you may contact the individual noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meetings as the Committee discusses the issues, and prior to deliberations and voting. There will also be a public comment period during the meeting on March 27, 2024, at approximately 12:30 p.m. (PDT). Public comments will be limited to 3 minutes per speaker and limited to one comment per person. Please note that the public comments period will end following the last call for comments. Please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to register as a speaker.

Dated: February 29, 2024.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2024–04777 Filed 3–5–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0824]

Request for Information; Extension of Comment Period

AGENCY: Coast Guard, DHS.

ACTION: Extension of comment period for request for information.

SUMMARY: The Coast Guard is extending the comment period of the Request for Information to collect opinions, ideas, recommendations, and concerns related to the Coast Guard's mandate to create planning criteria for vessel response plans (VRPs) distinct to the Western Alaska and Prince William Sound Captain of the Port (COTP) zones. The Coast Guard is tasked with developing planning criteria suitable for operating areas where response capability is currently inadequate.

DATES: Comments must be submitted to the online docket via *https://www.regulations.gov* on or before May 3, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0824 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Lieutenant Commander Adriana Gaenzle, U.S. Coast Guard; telephone 202–372–1226, email *Adriana.J.Gaenzle@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

The U.S. Coast Guard views public participation as essential to understanding vessel oil spill response planning and capabilities in remote areas of Alaska. The Coast Guard will consider all information and material received during the comment period. If you submit a comment, please include the docket number for this request for information, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Methods for submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *www.regulations.gov.* To do so, go to *www.regulations.gov,* type USCG–2023–0824 in the search box, and click

''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this notice as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Discussion

The Request for Information was published on December 4, 2023. 88 FR 84157. The original comment period will close on March 4, 2024. However, the Coast Guard has been notified that several stakeholders would like more time to prepare their comments for the Request for Information. The Coast Guard has decided that an extension of the public comment period would be appropriate to allow interested parties additional time to submit comments for Coast Guard's consideration. Thus, Coast Guard is extending the comment period by 60 days, until May 3, 2024.

Dated: February 28, 2024.

D.S. Tulis,

Director, Emergency Management, U.S. Coast Guard.

[FR Doc. 2024–04680 Filed 3–5–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

[245D0107SL D2L000000.000000 DL9CSHQS00; OMB Control Number 1092–NEW]

Agency Information Collection Activities; Office of the Solicitor Internship/Externship Application Process

AGENCY: Office of the Solicitor, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of the Solicitor (SOL) are proposing a new information collection in use without OMB approval.

DATES: Interested persons are invited to submit comments on or before May 6, 2024.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Ariana Rigsby, 1849 C Street NW, MS 6551, Washington, DC 20240; or by email to *hr-sol@sol.doi.gov.* Please reference OMB Control Number 1092–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Ariana Rigsby by email at *hr-sol@sol.doi.gov,* or by telephone at (202) 740–0269. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The following information is collected: applicant's resume with two professional or academic references, a completed Request for Consideration form (to designate the locations/offices for which the applicant would like to be considered for an internship), a cover letter addressed to ''To Whom it May Concern,'' a copy of the applicant's most recent law school transcript (official or unofficial), and a writing sample of no more than three (3) pages. The information is collected for the purpose of applying to SOL's Legal Internship/Externship Program. The information is used to verify the applicant's eligibility, interest in the program, and the location/office they wish to be considered for an internship.

Title of Collection: Office of the Solicitor, Legal Internship/Externship Program.

OMB Control Number: 1092–NEW.

Form Number: None.

Type of Review: New, in use without approval.

Respondents/Affected Public: Individuals (law school students).

Total Estimated Number of Annual Respondents: 200.

Total Estimated Number of Annual Responses: 200.

Estimated Completion Time per Response: 2 hours.

Total Estimated Number of Annual Burden Hours: 400 Hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Marc A. Smith,

Associate Solicitor—Administration.

[FR Doc. 2024–04683 Filed 3–5–24; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NV_FRN_MO4500177889]

Notice of Application for Extension of Withdrawal of Public Lands for Runway Safe Zone, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States Air Force has requested that the Secretary of the Interior extend the withdrawal established by Public Land Order (PLO) No. 7613 for an additional 20-year term. PLO No. 7613 withdrew 40 acres of public lands from settlement, sale, location, or entry under the general land laws, including the United States mining laws, subject to valid existing rights, for a period of 20 years, to protect a runway safe zone at Nellis Air Force Base located in Las Vegas, Nevada. This notice advises the public of an opportunity to comment on the U.S. Air Force application for extension of the withdrawal and to request a public meeting.

DATES: Comments and recommendations for a public meeting regarding the withdrawal extension application must be received on or before June 4, 2024.

ADDRESSES: Comments and meeting requests should be sent to the Bureau of Land Management (BLM) Las Vegas Field Manager, 4701 North Torrey Pines Dr., Las Vegas, NV 89130.

FOR FURTHER INFORMATION CONTACT: Eric Benavides, Realty Specialist, BLM Las Vegas Field Office, at (702) 515–5144, email: *ebenavides@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or Tele Braille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The withdrawal established by PLO No. 7613 on August 18, 2004 (69 FR 51320), and serialized as N–74668 (NVNV10 6080782), is incorporated herein by reference and will expire on August 17, 2024, unless extended as requested by the U.S. Air Force. The purpose of the withdrawal is to protect a runway safe zone at Nellis Air Force Base.

The 40 acres of public lands are located wholly within Nellis Air Force Base, a secured military installation, at the northern end of an active runway; public access to these lands has been restricted since the 1950's. The 40 acres withdrawn by PLO No. 7613 are in the northeast portion of Las Vegas, Nevada, east of Las Vegas Blvd., and are legally described as:

Mount Diablo Meridian, Nevada

T. 19 S., R. 62 E.,
Sec. 35, SE¼SW¼.

The area described contains 40.00 acres, according to the official plats of the surveys of the said lands, on file with the BLM.

Comments, including name and street address of respondents, will be available for public review at the BLM Las Vegas Field Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130, during regular business hours 8:00 a.m. to 4:00 p.m., Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you may ask the BLM in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the application for withdrawal extension. All interested persons who desire a public meeting for the purpose of being heard on the application for withdrawal extension must submit a written request to the Field Manager, BLM Las Vegas Field Office, at the address in the **ADDRESSES** section, within 90 days from the date of publication of this notice. If the authorized officer determines that a public meeting will be held, a notice of the date, time, and place will be published in the **Federal Register**, local newspapers, and on the BLM website at *www.blm.gov* at least 30 days before the scheduled date of any meeting.

This withdrawal extension application will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

(Authority: 43 CFR 2310.4)

Jon K. Raby,

State Director, Nevada.

[FR Doc. 2024–04714 Filed 3–5–24; 8:45 am]

BILLING CODE 4331–21–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037520; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Chemawa (Salem) Indian School in Marion County, OR.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, one individual was collected at the Chemawa (Salem) Indian School,

Marion County, OR. The human remains are hair clippings collected from one individual who was recorded as being 15 years old and identified as ''Siletz.'' James T. Ryan took the hair clippings at the Chemawa (Salem) Indian School between 1930 and 1933. Ryan sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Confederated Tribes of Siletz Indians of Oregon.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

This notice was submitted after the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024) but in the older format. As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04658 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037537; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Michigan History Center, Lansing, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Michigan History Center has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes in this notice. The human remains and associated funerary objects were removed from Allen County, IN.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 5, 2024.

ADDRESSES: Tobi Voigt, Director of Museums, Michigan History Center, 702 W. Kalamazoo St., Lansing, MI 48915, telephone (517) 243–4041, email *VoigtT@Michigan.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Michigan History Center. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Michigan History Center.

Description

Human remains representing, at minimum, one individual were removed from Allen County, IN. On an unknown date in 1912, Joseph Edinger was said to have excavated the burial site of the Miami leader, Little Turtle. A braid of hair with silver buckles was donated to the Michigan History Center. According to the Michigan History Center's records, most of what Edinger excavated from the burial site was said to have been donated to the Smithsonian Museum in Washington, DC, but this is unconfirmed, and no further details are known. The one associated funerary object is one lot of silver buckles.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes. The following types of information were used to reasonably trace the relationship: historical information, other relevant information, or expert opinion.

Lineal Descent

The human remains and associated funerary objects in this notice are connected to an identifiable individual whose descendants can be traced directly and without interruption by means of a traditional kinship system or by the common law system of descendance. The following types of information were used to reasonably trace the relationship: historical information, other relevant information, or expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, the Michigan History Center has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The one lot of objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably

traced between the human remains and associated funerary objects described in this notice to Daryl Baldwin (Miami Tribe of Oklahoma) and Scott Willard (Miami Tribe of Oklahoma).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.

2. Any lineal descendant or Indian Tribe not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Michigan History Center must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary object are considered a single request and not competing requests. The Michigan History Center is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04667 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037532; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: New York State Office of Parks, Recreation, & Historic Preservation, Waterford, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the New York State Office of Parks, Recreation, & Historic Preservation (NYOPRHP) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Alton, Madison County, IL.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 5, 2024.

ADDRESSES: Jessica Vavrasek, New York State Office of Parks, Recreation & Historic Preservation, Peebles Island State Park, P.O. Box 189, Waterford, NY 12188–0189, telephone (518) 268–2199, email *Jessica.Vavrasek@parks.ny.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the NYOPRHP. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the NYOPRHP.

Description

In 1876, human remains representing, at minimum, six individuals were removed from Alton in Madison County, IL, by Reverend Robert West. Artifacts recovered from this informal excavation were later transferred to William Letchworth at an unknown point. The 29 associated funerary objects are 27 bones (identified as belonging to a white-tailed deer that represent at least four adults and two immature deer), one whale cervical vertebral body, and one black stone/ceramic pipe stem fragment (approx.10mm in length).

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological information, archeological information, and geographical information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the NYOPRHP has determined that:

- The human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- The 29 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Peoria Tribe of Indians of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the NYOPRHP must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The NYOPRHP is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the

National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04665 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037521; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Yager Museum of Art & Culture, Hartwick College, Oneonta, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Yager Museum of Art & Culture, Hartwick College (hereafter ''Yager Museum'') intends to repatriate a certain cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after April 5, 2024.

ADDRESSES: Dr. Quentin Lewis, Yager Museum of Art & Culture, Hartwick College, 1 Hartwick Drive, Oneonta, NY 13820, telephone (607) 431–4481, email *lewisq@hartwick.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Yager Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

One cultural item has been requested for repatriation. The object is a bear claw necklace, consisting of a small leather thong or strap, which is threaded through punctured holes in each of two bear claws. This necklace was originally in the collection of Townsend Bishop (1867–1950) of Colliersville, NY. It is unclear how Mr. Bishop acquired this necklace. This collection was purchased by Rowan Spraker Sr. of Cooperstown, NY, before joining the Yager Museum's collection in 1963. Museum records indicate that this necklace was made by the Ute, and subsequent research and consultation has supported this affiliation, as well as the culturally patrimonial status of this object to the Ute people.

Determinations

The Yager Museum has determined that:

- *Objects of Cultural Patrimony:* The one object described in this notice has ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural item described in this notice and the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Ute Tribe.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Yager Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Yager Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04659 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037530; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Milwaukee Public Museum, Milwaukee, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Milwaukee Public Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Marinette County, WI.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 5, 2024.

ADDRESSES: Dawn Scher Thomae, Milwaukee Public Museum, 800 W Wells Street, Milwaukee, WI 53233, telephone (414) 278–6157, email *thomae@mpm.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Milwaukee Public Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Milwaukee Public Museum.

Description

Human remains representing, at minimum, one individual were removed from Marinette County, WI. In 1964, historic burials were excavated at the Potato Rapids site (47–MT–79) located along the Peshtigo River just upstream of the Highway-64 Bridge near the town of Peshtigo and the Potato Rapids power plant in Porterfield Township,

Marinette County, WI. Members of the Wisconsin Archaeological Society conducted the excavations under the supervision of Robert J. Hruska, then Curator of Anthropology at the Oshkosh Public Museum. The individual was then donated to the Milwaukee Public Museum by Hruska and the Wisconsin Archaeological Society on June 6th, 1967. The individual is a complete female that has associated funerary objects in a suspended matrix within a plaster jacket and two metal poles attached along the length serve as handles for transport. The 12 associated funerary objects include birch bark fragments, two silver brooches, one lot of black glass beads (≤50), fabric fragments, a metal cup, a belt buckle, a knife handle or pocketknife, a saucer or plate, brooch or gorget, metal fragments, and fur fragments.

The Potato Rapids Burial site (47–MT–79) is located within the ancestral territory of the Menominee Indian Tribe of Wisconsin and within the area occupied by the Menominee during the early to mid-19th century. According to the Treaty with the Menominee of 1836, a section of land including the site was ceded by the Menominee to the United States Federal Government. Additionally, a map of Indian Villages c. 1830 in the Wisconsin Region of Michigan Territory from Helen Hornbeck Tanner's book, ''Atlas of Great Lakes Indian History'', shows several Menominee villages located in the vicinity of the site. In 2000, a burial from the same site was affiliated with and repatriated to the Menominee Indian Tribe of Wisconsin by the Oshkosh Public Museum.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical information, historical information, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Milwaukee Public Museum has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The 12 objects described in this notice were placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Menominee Indian Tribe of Wisconsin.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Milwaukee Public Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Milwaukee Public Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04663 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037519; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, 18 individuals have been reasonably identified. No associated funerary objects are present. Human remains representing, at minimum, 15 individuals were collected at the Flandreau Indian School, Moody County, SD. The human remains are hair clippings collected from one individual who was recorded as being 18 years old, one individual who was recorded as being 17 years old, three individuals who were recorded as being 16 years old, five individuals who were recorded as being 15 years old, one individual who was recorded as being 14 years old, three individuals who were recorded as being 13 years old, and one individual who was recorded as being 11 years old and identified as

''Chippewa.'' George E. Peters took the hair clippings at the Flandreau Indian School between 1930 and 1933. Peters sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Human remains representing, at minimum, one individual was collected at the Standing Rock School, Sioux County, ND. The human remains are hair clippings collected from one individual who was recorded as being 36 years old and identified as ''Chippewa.'' E.D. Mossman took the hair clippings at the Standing Rock School between 1930 and 1933. Mossman sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Human remains representing, at minimum, two individuals were collected at the Cass Lake Chippewa Agency, Cass County, MN. The human remains are hair clippings collected from one individual who was recorded as being 67 years old and one individual who was recorded as being 24 years old and identified as ''Chippewa.'' M.L. Burns took the hair clippings at the Cass Lake Chippewa Agency between 1930 and 1933. Burns sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The PMAE has determined that:

- The human remains described in this notice represent the physical remains of 18 individuals of Native American ancestry.
- There is a reasonable connection between the human remains and associated funerary objects described in this notice and the Minnesota Chippewa Tribe, Minnesota (White Earth Band).

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04657 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037539; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Mercyhurst University, Erie, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Mercyhurst University has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from an unknown geographic location in AR.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Anne Marjenin, Mercyhurst University, 501 E 38th Street, Erie, PA 16546, telephone (814) 824–2012, email *nagpra@mercyhurst.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Mercyhurst University. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by Mercyhurst University.

Description

Human remains representing, at minimum, one individual were removed from an unknown geographic location in AR. The individual (V–MAN–0215) was collected on an unknown date and was obtained by Raymond C. Vietzen (1907–1995). Vietzen, an avocational archeologist, collector, and author, established the Indian Ridge Museum in Elyria, Ohio, and the Archaeological Society of Ohio (formerly the Ohio Indian Relic Collectors Society). The Indian Ridge Museum, founded in the 1930s, served as Vietzen's laboratory and repository, and it remained in operation until the mid-1990s. After Vietzen's death, the facility fell into disrepair, and most of the items he had acquired and housed at the museum were sold. In 1998, the Ohio Historical Society (presently the Ohio History Connection) removed ancestral human remains and some of the remaining items from the facility and temporarily housed them at the Ohio Historical Society. In October of 2003, these human remains were transferred from the Ohio Historical Society to Mercyhurst College (presently Mercyhurst University). No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical and other relevant information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, Mercyhurst University has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Caddo Nation of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, Mercyhurst University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. Mercyhurst University is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04668 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037522; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Tennessee, Department of Anthropology, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Tennessee, Department of Anthropology (UTK), has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Jackson County, MO.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Dr. Ozlem Kilic, University of Tennessee, Office of the Provost, 527 Andy Holt Tower, Knoxville, TN 37996–0152, telephone (865) 974–2454, email *okilic@utk.edu* and *vpaa@utk.edu*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UTK. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by UTK.

Description

Sometime before 1968, human remains representing, at minimum, one individual were removed from Fort Osage (23JA45), in Jackson County, MO by an unknown party. Based on a past pattern of practice, it is likely that this individual was transferred to William Bass for analysis, possibly while he was at the University of Kansas, and subsequently brought by him to Knoxville when he began working at UTK in 1971. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archaeological information, geographical information, historical information, linguistics, and oral tradition.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, UTK has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and The Osage Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, UTK must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. UTK is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04660 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037541; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Mercyhurst University, Erie, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Mercyhurst University has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations

in this notice. The human remains were removed from Crawford County, AR.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Anne Marjenin, Mercyhurst University, 501 E 38th Street, Erie, PA 16546, telephone (814) 824–2012, email *nagpra@mercyhurst.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Mercyhurst University. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by Mercyhurst University.

Description

Human remains representing, at minimum, one individual were removed from Crawford County, AR. The individual (VM–079) was collected on an unknown date and was obtained by Raymond C. Vietzen (1907–1995). Vietzen, an avocational archeologist, collector, and author, established the Indian Ridge Museum in Elyria, Ohio, and the Archaeological Society of Ohio (formerly the Ohio Indian Relic Collectors Society). The Indian Ridge Museum, founded in the 1930s, served as Vietzen's laboratory and repository, and it remained in operation until the mid-1990s. After Vietzen's death, the facility fell into disrepair and most of the items he had acquired and housed at the museum were sold. In 1998, the Ohio Historical Society (presently the Ohio History Connection) removed ancestral human remains and some of the remaining items from the facility and temporarily housed them at the Ohio Historical Society. In October of 2003, these human remains and items were transferred from the Ohio Historical Society to Mercyhurst College (presently Mercyhurst University). No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, linguistics, and oral tradition.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, Mercyhurst University has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Caddo Nation of Oklahoma and The Osage Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, Mercyhurst University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. Mercyhurst University is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04669 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

[NPS–WASO–NAGPRA–NPS0037515; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Ball State University (BSU), David Owsley Museum of Art (DOMA), Muncie, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the David Owsley Museum of Art of Ball State University (DOMA) intends to repatriate certain cultural items that meet the definition of sacred objects and objects of cultural patrimony and that have a cultural affiliation with the Indian Tribe identified in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after April 5, 2024.

ADDRESSES: Chyan Gilaspy, Ball State University, Applied Anthropology Laboratories, 2000 W Riverside Avenue, Muncie, IN 47306, telephone (765) 285–5362, email *NAGPRA@bsu.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of DOMA, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of seven cultural items have been requested for repatriation. The sacred objects/objects of cultural patrimony are five basket hats, one basket with a lid, and one basket. The seven cultural items were removed from an unknown county and state, likely originating from Northern California and/or Southern Oregon. In 1983, a private individual donated five of the objects of cultural patrimony/sacred objects (four basket hats, one basket with lid) to DOMA. These are identified by DOMA catalog numbers 1983.006.003, 1983.006.004a, 1983.006.004b, 1983.006.005a–b, and 1983.006.059. In 2018, the estate of a private individual bequeathed two of the objects of cultural patrimony/sacred objects (one basket hat and one basket) to DOMA. These are identified by DOMA catalog numbers 2018.052.022 and 2018.052.024. No information is available for any of the objects concerning the dates of creation, donor

acquisition history, or previous treatments of hazardous substances.

Determinations

DOMA has determined that:

• The seven sacred objects/objects of cultural patrimony described in this notice are, according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization, specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, and have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision).

• There is a reasonable connection between the cultural items described in this notice and the Resighini Rancheria, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, DOMA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The DOMA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04653 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037535; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California, Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Berkeley has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Morrow County, OR.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Alexandra Lucas, Repatriation Coordinator, Government and Community Relations (Chancellor's Office), University of California, Berkeley, 200 California Hall, Berkeley, CA 94720, telephone (510) 570–0964, email *nagpra-ucb@berkeley.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California, Berkeley. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the University of California, Berkeley.

Description

Human remains representing, at minimum, two individuals were removed from two known locations in Morrow County, Eastern Oregon (designated OR-Morrow-NL–1 and OR-Morrow-NL–2) before 1940, and donated to the Lowie Museum (Phoebe A. Hearst Museum of Anthropology) by Mr. Bentley Wells. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: Tribal traditional knowledge, geographical, anthropological, archaeological, kinship, biological, linguistic, folklore, historical, and oral history.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the University of California, Berkeley has determined that:

• The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.

• There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Confederated Tribes of the Umatilla Indian Reservation; Confederated Tribes of the Warm Springs Reservation of Oregon; and the Nez Perce Tribe.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the University of California, Berkeley must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The University of California, Berkeley is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted after the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024) but in the older format. As the notice conforms to the mandatory format of the **Federal Register** and includes the required

information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04666 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037543; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Land Management, Winnemucca District Office, Winnemucca, NV

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Land Management, Winnemucca District Office has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Washoe County, NV.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Cedric Streater, Bureau of Land Management, 5100 E. Winnemucca Boulevard, Winnemucca, NV 89445, telephone (775) 623–1595, email *cstreater@blm.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Winnemucca District Office. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Winnemucca District Office.

Description

Human remains representing, at minimum, five individuals were removed from Washoe County, NV. The human remains consisted of five incomplete individuals: one adult male; one young adult male approximately 20–35 years old; one young adult male; one youth, possibly male, approximately 15–20 years old; and one child. These human remains were originally cataloged by the Hearst Museum under Accession 1030 and their catalog number is 12–8369. At the request of the Pyramid Lake Paiute Tribe, these human remains were transferred to the Nevada State Museum (NSM) in 2012. The NSM catalog numbers for the human remains are AHUR 6019 through 6023.

The Bureau of Land Management recently became aware of Native American human remains collected prior to November 16, 1990, on lands administered by the BLM. The human remains were reported as culturally unidentifiable on June 19, 2003, by the Phoebe A. Hearst Museum of Anthropology (Hearst Museum). In November 2011, the BLM became aware of previously unreported Native American human remains through a letter from the Pyramid Lake Paiute Tribe requesting BLM involvement in assisting with the repatriation of remains being held at the Hearst Museum. The remains were collected sometime in 1947–1948 near Winnemucca Lake Caves in Nevada and received by the Hearst Museum in 1948. According to the records of the Hearst Museum, this material was reported in their Washoe County Inventory, dated June 28, 2000. In a closer review of the locality documentation, it was determined the material is under the control of the BLM.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical information and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Winnemucca District Office has determined that:

- The human remains described in this notice represent the physical remains of five individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Bishop Paiute Tribe; Bridgeport Indian Colony; Burns Paiute Tribe; Cedarville Rancheria, California; Confederated Tribes of the Warm Springs Reservation of Oregon; Fort Bidwell Indian Community of the Fort Bidwell Reservation of California; Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Klamath Tribes; Lone Pine Paiute-Shoshone Tribe; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada; Reno-Sparks Indian Colony, Nevada; Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada; Summit Lake Paiute Tribe of Nevada; Susanville Indian Rancheria, California; Battle Mountain Band, Nevada; Te-Moak Tribe of Western Shoshone Indians of Nevada (Battle Mountain Band); Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, Nevada; Walker River Paiute Tribe of the Walker River Reservation, Nevada; Winnemucca Indian Colony of Nevada; and the Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Winnemucca District Office must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Winnemucca District Office is responsible for sending a copy of this notice to the Indian Tribes and Native

Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04671 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037529; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition: General Services Administration, Pacific Rim Region, Design & Construction Division, San Francisco, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the General Services Administration, Pacific Rim Region, Design & Construction Division (GSA), intends to carry out the disposition of human remains removed from Federal lands to the Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains in this notice may occur on or after April 5, 2024. If no claim for disposition is received by March 6, 2025, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Jason Hagin, Regional Historic Preservation Officer, Design & Construction Division, 50 United Nations Plaza, MB9, Room 3411, San Francisco, CA 94102, telephone (415) 244–7760, email *1445ason.hagin@gsa.gov*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of GSA, and additional information on the human remains in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, fragments of human remains representing an unknown number of individuals have been reasonably identified. No associated funerary objects are present. No unassociated funerary objects, sacred objects, or objects of cultural patrimony are present.

Determinations

GSA has determined that:

- The fragments of human remains described in this notice do not reflect an intact burial site and represent the physical remains of an unknown number of individuals of Native Hawaiian ancestry.
- 'Ohana Keaweamahi has priority for disposition of the human remains described in this notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by March 6, 2025, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant or Native Hawaiian organization identified in this notice.

2. Any lineal descendant or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that they have priority for disposition.

Disposition of the human remains in this notice may occur on or after April 5, 2024. If competing claims for disposition are received, GSA must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. GSA is responsible for sending a copy of this notice to the lineal descendants and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04662 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037531; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Defense, Defense Health Agency, National Museum of Health and Medicine, Silver Spring, MD

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of Defense, Defense Health Agency, National Museum of Health and Medicine has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Jackson County, AL; Christian County, KY; McLean County, KY; Ohio County, KY; Union County, KY; Hamilton County, TN; Sevier County, TN; and Kanawha County, WV.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Mr. Brian F. Spatola, Curator of Anatomical Division, National Museum of Health and Medicine, U.S. Army Garrison Forest Glen, 2500 Linden Lane, Silver Spring, MD 20910, telephone (301) 319–3353, email *brian.f.spatola.civ@health.mil.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the National Museum of Health and Medicine. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the National Museum of Health and Medicine.

Description

Human remains representing, at minimum, two individuals were removed from Jackson County, AL. The human remains consist of a humerus removed from the Garland's Ferry site, and a femur and humerus removed from the William's Landing site by Clarence B. Moore. The human remains were donated to the Army Medical Museum (today the National Museum of Health

and Medicine) by Clarence B. Moore in May 1915. No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from Christian County, KY. The human remains consist of a cranium with no known collection history. ''MCR–64/Chr. Co, KY'' and ''KY–1964'' are written on the cranium in black ink. The human remains were donated to the National Museum of Health and Medicine in 2003. No associated funerary objects are present.

Human remains representing, at minimum, two individuals were removed from McLean County, KY. The remains consist of a femur and tibia removed from the Austin Place site, and a radius removed from the Calhoun site by Clarence B. Moore. The human remains were donated to the Army Medical Museum by Clarence B. Moore in April 1916. No associated funerary objects are present.

Human remains representing, at minimum, 12 individuals were removed from Ohio County, KY. The human remains consist of multiple skeletal elements removed from the Indian Knoll site by Clarence B. Moore. The human remains were donated to the Army Medical Museum by Clarence B. Moore in 1916. No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from Union County, KY. The human remains consist of a partial cranium that was collected by Sydney S. Lyon. Initially, these human remains were donated to the Smithsonian Institution. In January 1870, they were transferred to the Army Medical Museum. No associated funerary objects are present.

Human remains representing, at minimum, four individuals were removed from Hamilton County, TN. The human remains consist of a tibia removed from Hampton Place at Moccasin Bend, and an ulna, radius, and two tibiae removed from the Citico Mound site by Clarence B. Moore. The human remains were donated to the Army Medical Museum by Clarence B. Moore in 1915. No associated funerary objects are present.

Human remains representing, at minimum, three individuals were removed from Sevier County, TN. The human remains consist of a sternum, fibula, and tibia removed from McMahan Mound by E. Palmer in 1881. Initially, these human remains were donated to the Smithsonian Institution. In July 1886, they were transferred to the Army Medical Museum. No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from Kanawha County, WV. The human remains consist of a tibia removed from Smith's Farm near Charleston by P. W. Norris. Initially, these human remains were donated to the Smithsonian Institution. In 1904, they were transferred to the Army Medical Museum. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological information, geographical information, and historical information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the National Museum of Health and Medicine has determined that:

- The human remains described in this notice represent the physical remains of 26 individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the National Museum of Health and Medicine must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The National Museum of Health and Medicine is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04664 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037526; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition: U.S. Army Corps of Engineers, St. Louis District, St. Louis, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Army Corps of Engineers, St. Louis District, intends to carry out the disposition of human remains, associated funerary objects, unassociated funerary objects, sacred objects, or objects of cultural patrimony removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains or cultural items in this notice may occur on or after April 5, 2024. If no claim for disposition is received by March 6, 2025, the human remains or cultural items in this notice will become unclaimed human remains or cultural items.

ADDRESSES: Jenna Domeischel, U.S. Army Corps of Engineers, St. Louis District, 1222 Spruce Street, ATTN:

CEMVS–EC–Z, St. Louis, MO 63103, telephone (314) 331–8840, email *jenna.domeischel@usace.army.mil.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the U.S. Army Corps of Engineers, St. Louis District, and additional information on the human remains or cultural items in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

The 55 associated funerary objects are two lots of soil, 41 ceramics, two shell fragments, seven lithics, one groundstone, and two small rocks. In July 2017, human remains and associated funerary objects were discovered at Mark Twain Lake, Monroe County, Missouri, by a member of the public. These remains and one associated funerary object were previously reported in a newspaper notice in 2023 (*Hannibal Courier-Post* on September 20 and 27 and *Tulsa World* on November 1 and 8). The remains and objects are currently stored at a secure location in the St. Louis District laboratory.

Determinations

The U.S. Army Corps of Engineers, St. Louis District, has determined that:

- The 55 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- The U.S. Army Corps of Engineers, St. Louis District, has identified The Osage Nation as having priority for disposition of the cultural items described in this notice.

Claims for Disposition

Written claims for disposition of the human remains or cultural items in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by March 6, 2025, the human remains or cultural items in this notice will become unclaimed human remains or cultural items. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that they have priority for disposition.

Disposition of the human remains or cultural items in this notice may occur on or after April 5, 2024. If competing claims for disposition are received, the U.S. Army Corps of Engineers, St. Louis District, must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains or cultural items are considered a single request and not competing requests. The U.S. Army Corps of Engineers, St. Louis District, is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04661 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037518; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a known lineal descendant connected to the human remains in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, one individual have been reasonably identified. No associated funerary objects are present. The human remains were collected at the Sherman Institute, Riverside County, CA, and are hair clippings collected from one individual, Rudolph Aguilar, who was recorded as being 18 years old and identified as ''Mission.'' Samuel H. Gilliam took the hair clippings at the Sherman Institute between 1930 and 1933. Gilliam sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Lineal Descendant

Based on the information available and the results of consultation, a lineal descendant is connected to the human remains described in this notice.

Determinations

The PMAE has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- A known lineal descendant Michelle Aguilar-Wells is connected to the human remains described in this notice.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. The known lineal descendant connected to the human remains.

2. Any other lineal descendant not identified who shows, by a preponderance of the evidence, that the requestor is a lineal descendant.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the lineal descendant and the

consulting Indian Tribes or Native Hawaiian organizations.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04656 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037516; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 5, 2024.

ADDRESSES: Laura Bryant, Gilcrease Museum, 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual has been reasonably identified. The 24 associated funerary objects are 19 lots of lithic tools, one lot of faunal remains, two shell cups, one lot of shell and copper beads, and one lot of sherds. Frank Soday, an avocational archaeologist, from ''Grave Island'' in Limestone County, AL in 1951. Gilcrease Museum acquired Soday's collection in 1982.

Based on the information available, human remains representing, at least, one individual has been reasonably identified. The 33 associated funerary objects are one lot of sherds and 32 lots of lithic tools. Frank Soday, an avocational archaeologist, from ''Peninsula West of Chemstrand Point'' in Morgan County, AL in 1952. Gilcrease Museum acquired Soday's collection in 1982.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location of the human remains and associated funerary objects described in this notice.

Determinations

The Gilcrease Museum has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- The 57 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a reasonable connection between the human remains and associated funerary objects described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; The Chickasaw Nation; The Muscogee (Creek) Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Gilcrease Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04654 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037542; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Central Washington University, Ellensburg, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Central Washington University has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Klickitat County, WA.

DATES: Repatriation of the human remains in this notice may occur on or after April 5, 2024.

ADDRESSES: Lourdes Henebry-DeLeon, Department of Anthropology and Museum Studies, Central Washington University, 400 University Way, Ellensburg, WA 98926–7544, telephone (509) 963–2671, email *Lourdes.Henebry-DeLeon@cwu.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Central Washington University. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by Central Washington University.

Description

Human remains representing, at minimum, one individual were removed from Yakima County, WA. The Yakima County Coroner's Office found the human remains in 2000 or 2001 and subsequently donated them to Central Washington University. The Coroner's Office has no information about their origins. The King County Medical Examiner's Forensic Anthropologist determined the human remains to be non-forensic. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: biological, geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, Central Washington University has determined that:

- The human remains described in this notice represent the physical remains of one individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Confederated Tribes and Bands of the Yakama Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, Central Washington University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. Central Washington University is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04670 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037517; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum intends to repatriate certain cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after April 5, 2024.

ADDRESSES: Laura Bryant, Gilcrease Museum, 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of two cultural items have been requested for repatriation. The two objects of cultural patrimony are a robe and a mat. J.A. Wyrick and Frank Weddington removed these items from Piney Creek Bluff Shelter in Carroll County, AR in 1935. Harry Lemley acquired these from them later that same year. Thomas Gilcrease purchased Lemley's collection, including these items, in 1950, and Gilcrease transferred his collection to the City of Tulsa in 1955.

A total of one cultural item has been requested for repatriation. The one object of cultural patrimony is a bald cypress pole fragment. James Porter removed the item from the Mitchell Mound site in Madison County, Illinois in the 1960s. Gilcrease Museum acquired the item shortly after.

Determinations

The Gilcrease Museum has determined that:

- The three objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and The Osage Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 5, 2024. If competing requests for repatriation are received, the Gilcrease Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a

copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: February 27, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–04655 Filed 3–5–24; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1392]

Certain Oil Vaporizing Devices, Components Thereof, and Products Containing the Same; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on January 30, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of PAX Labs Inc. of San Francisco, California. Supplements were filed on February 19, 2024, February 20, 2024, and February 21, 2024. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain oil vaporizing devices, components thereof, and products containing the same by reason of the infringement of certain claims of U.S. Patent No. 11,369,756 (''the '756 patent''); U.S. Patent No. 11,369,757 (''the '757 patent''); U.S. Patent No. 11,766,527 (''the '527 patent''); 11,759,580 (''the '580 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2023).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on February 29, 2024, ORDERED THAT—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–3, 5–13, and 15–17 of the '756 patent; claims 1–20 of the '757 patent; claims 1–30 of the '527 patent; and claims 1–20 of the '580 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''vaporizing devices capable of vaporizing oils, components thereof and products containing the same'' where the components of a vaporizing device are ''a mouthpiece, a cartridge body, an atomizer, a distal member, a bottom cover, a vaporizer body including a cartridge receiver,'' as well as a ''battery,'' and where products containing the same are cartridge and battery components ''sold in combination with a power charging device in which the [cartridge] or battery would each be one component of the downstream product'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

PAX Labs Inc., 660 Alabama Street, Second Floor, San Francisco, CA, 94110

(b) The respondents are the following entities alleged to be in violation of section 337, and is the parties upon which the complaint is to be served:

STIIIZY IP LLC f/k/a STIIIZY, LLC, 728 East Commercial Street, Los Angeles, CA 90012

ALD Group Limited, No. 2 Industrial Third Road, Tangtou Community, Shiyan Street, Bao'an District, Shenzhen, Guangdong Province, China 518108

ALD (Hong Kong) Holdings Limited, 19H Maxgrand Plaza No. 3, Tai Yau Street, San Po Kong, Kowloon, Hong Kong

STIIIZY Inc. d/b/a Shryne Group Inc., 2001 South Alameda Street, Los Angeles, CA 90058; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not be a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: February 29, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–04705 Filed 3–5–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–693 and 731–TA–1629–1640 (Final)]

Mattresses From Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations.

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–693 and 731–TA–1629–1640 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of mattresses, provided for in subheadings 9404.21.00, 9404.29.10, and 9404.29.90 of the Harmonized Tariff Schedule of the United States, from Bosnia and Herzegovina, Bulgaria, Burma, India, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan preliminarily determined by the Department of Commerce (''Commerce'') to be sold at less than fair value and imports of mattresses from Indonesia for which Commerce has preliminarily determined that countervailable subsidies are not being provided by the Government of Indonesia to producers and exporters of mattresses from Indonesia.

DATES: March 1, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Messer ((202) 205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as follows:

The products covered by these investigations are all types of youth and adult mattresses. The term ''mattress'' denotes an assembly of materials that at a minimum includes a ''core,'' which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses also may contain: (1) ''upholstery,'' the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) ''ticking,'' the outermost layer of fabric or other material (*e.g.,* vinyl) that encloses the core and any upholstery, also known as a cover.[1]

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of a negative preliminary determination by Commerce regarding whether certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in Indonesia of mattresses, and affirmative preliminary determinations by Commerce that such products imported from Bosnia and Herzegovina, Bulgaria, Burma, India, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on July 28, 2023, on behalf of Brooklyn Bedding LLC, Phoenix, Arizona; Carpenter Company, Richmond, Virginia; Corsicana Mattress Company, Dallas, Texas; Future Foam, Inc., Council Bluffs, Iowa; FXI, Inc., Radnor, Pennsylvania; Kolcraft Enterprises, Inc., Chicago, Illinois; Leggett & Platt, Incorporated, Carthage, Missouri; Serta Simmons Bedding, Inc., Doraville, Georgia; Southerland Inc., Antioch, Tennessee; Tempur Sealy International, Inc., Lexington, Kentucky; the International Brotherhood of Teamsters, Washington, DC; and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, Washington, DC.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Although Commerce has preliminarily determined that countervailable subsidies are not being provided by the Government of Indonesia to producers and exporters of mattresses from Indonesia, for purposes of efficiency the Commission hereby waives rule 207.21(b)[2] so that the final phase of the investigation may proceed concurrently in the event that Commerce makes a final affirmative countervailing duty determination with respect to such imports.

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

[1] For a complete definition of mattresses, including exclusions and tariff treatment, see 89 FR 57–59, January 2, 2024, and 89 FR 15121–15124, 15126–15134, 15136–15157, 15161–15164, March 1, 2024.

[2] § 207.21(b) of the Commission's rules provides that, where Commerce has issued a negative preliminary determination, the Commission will publish a Final Phase Notice of Scheduling upon receipt of an affirmative final determination from Commerce.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record by 5:15 p.m. on April 26, 2024, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on May 9, 2024. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission by 5:15 p.m. on May 3, 2024. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigations, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on May 7, 2024. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than 4:00 p.m. on May 8, 2024. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is 5:15 p.m. on May 3, 2024. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is 5:15 p.m. on May 16, 2024. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petitions, by 5:15 p.m. on May 16, 2024. On June 4, 2024, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information by 5:15 p.m. on June 6, 2024, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: March 1, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–04774 Filed 3–5–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–603]

Rice: Global Competitiveness and Impacts on Trade and the U.S. Industry

AGENCY: United States International Trade Commission.

ACTION: Notice of investigation and scheduling of a public hearing.

SUMMARY: Following receipt on February 5, 2024, of a request from the U.S. House of Representatives Committee on Ways and Means (Committee) under section 332(g) of the Tariff Act of 1930, the U.S. International Trade Commission (Commission) instituted Investigation No. 332–603, *Rice: Global Competitiveness and Impacts on Trade and the U.S. Industry.* The Committee requested that the Commission conduct an investigation and produce a report on the global competitiveness of the U.S. rice industry.

DATES:

April 8, 2024: Deadline for filing requests to appear at the public hearing.

April 11, 2024: Deadline for filing prehearing briefs and statements.

April 22, 2024: Deadline for filing electronic copies of oral hearing statements.

April 30, 2024: Public hearing.

May 22, 2024: Deadline for filing posthearing briefs.

July 12, 2024: Deadline for filing all other written submissions.

March 5, 2025: Transmittal of Commission report to the Committee.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's

electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Project Leader Renee Berry (202–205–3498 or *renee.berry@usitc.gov*) or Deputy Project Leaders Patrick Crotty (202–205–2224 or *patrick.crotty@usitc.gov*) and Tyler Daun (202–205–3329 or *tyler.daun@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact Brian Allen (202–205–3034 or *brian.allen@usitc.gov*) or William Gearhart (202–205–3091 or *william.gearhart@usitc.gov*) of the Commission's Office of the General Counsel. The media should contact Jennifer Andberg, Office of External Relations (202–205–3404 or *jennifer.andberg@usitc.gov*). Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. General information concerning the Commission may be obtained by accessing its internet address (*https://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background: As requested by the Committee, the Commission has instituted an investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) to produce a report on the global competitiveness of the U.S. rice industry. This report will contain updates to the Commission's 2015 report on the same topic (*Rice: Global Competitiveness of the U.S. Industry,* Pub. 4530) where significant changes have been observed during the 2018 to 2023 period. Specifically, the report will contain:

- information on recent developments in the rice industries in the United States and other major global producing and exporting countries, such as Bangladesh, Brazil, China, India, Indonesia, Pakistan, Paraguay, Thailand, Uruguay, and Vietnam;
- information on recent trade trends and developments in the global market for rice, including U.S. and major foreign supplier imports and exports;
- a comparison of the competitive strengths and weaknesses of rice production in and exports from the United States and other major exporting countries, focusing on factors affecting delivered cost, product differentiation, and reliability of supply, as well as government policies and programs that directly or indirectly affect rice production and exporting in these countries;
- a qualitative and, to the extent possible, quantitative assessment of the impact of government policies and programs, including public stockholding programs and export restrictions, of major producing and exporting countries on U.S. rice production, product revenues and profits, consumption, trade, and prices, as well as on food security in developing countries; and
- an overview of the impact on the U.S. rice industry of exports of rice from the highlighted countries to the United States and to traditional export markets of the United States.

As requested by the Committee, the Commission will deliver the report no later than March 5, 2025. The Committee asked that the Commission not include confidential business or national security classified information in its report. However, as detailed below, participants may submit confidential information to the Commission to inform its understanding of these issues, and such information will be protected in accordance with the Commission's *Rules of Practice and Procedure.* Participants are strongly encouraged to provide any supporting data and information along with their views.

Public Hearing: A public hearing in connection with this investigation will be held beginning at 9:30 a.m., April 30, 2024, in the Main Hearing Room of the U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The hearing can also be accessed remotely using the WebEx videoconference platform. A link to the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

Requests to appear at the hearing should be filed with the Secretary to the Commission no later than 5:15 p.m., April 8, 2024, in accordance with the requirements in the ''Written Submissions'' section below. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear as a witness via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigation, may at their discretion for good cause shown, grant such requests. Requests to appear as a witness via videoconference due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing.

All prehearing briefs and statements should be filed no later than 5:15 p.m., April 11, 2024. To facilitate the hearing, including the preparation of an accurate written public transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than noon, April 22, 2024. All posthearing briefs and statements should be filed no later than 5:15 p.m., May 22, 2024. Posthearing briefs and statements should address matters raised at the hearing. For a description of the different types of written briefs and statements, see the ''Definitions'' section below. In the event that, as of the close of business on April 8, 2024, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should check the Commission website as indicated above for information concerning whether the hearing will be held.

Written submissions: In lieu of or in addition to participating in the hearing, interested persons are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., July 12, 2024. All written submissions must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

Definitions of types of documents that may be filed; Requirements: In addition to requests to appear at the hearing, this notice provides for the possible filing of four types of documents: prehearing briefs, oral hearing statements, posthearing briefs, and other written submissions.

(1) *Prehearing briefs* refers to written materials relevant to the investigation and submitted in advance of the hearing, and includes written views on matters that are the subject of the investigation, supporting materials, and any other written materials that you

consider will help the Commission in understanding your views. You should file a prehearing brief particularly if you plan to testify at the hearing on behalf of an industry group, company, or other organization, and wish to provide detailed views or information that will support or supplement your testimony.

(2) *Oral hearing statements (testimony)* refers to the actual oral statement that you intend to present at the hearing. Do not include any confidential business information (CBI) in that statement. If you plan to testify, you must file a copy of your oral statement by the date specified in this notice. This statement will allow Commissioners to understand your position in advance of the hearing and will also assist the court reporter in preparing an accurate transcript of the hearing (*e.g.,* names spelled correctly).

(3) *Posthearing briefs* refers to submissions filed after the hearing by persons who appeared at the hearing. Such briefs: (a) should be limited to matters that arose during the hearing; (b) should respond to any Commissioner and staff questions addressed to you at the hearing; (c) should clarify, amplify, or correct any statements you made at the hearing; and (d) may, at your option, address or rebut statements made by other participants in the hearing.

(4) *Other written submissions* refers to any other written submissions that interested persons wish to make, regardless of whether they appeared at the hearing, and may include new information or updates of information previously provided.

In accordance with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8) the document must identify on its cover (1) the investigation number and title and the type of document filed (*i.e.,* prehearing brief, oral statement of (name), posthearing brief, or written submission), (2) the name and signature of the person filing it, (3) the name of the organization that the submission is filed on behalf of, and (4) whether it contains CBI. If it contains CBI, it must comply with the marking and other requirements set out below in this notice relating to CBI. Submitters of written documents (other than oral hearing statements) are encouraged to include a short summary of their position or interest at the beginning of the document, and a table of contents when the document addresses multiple issues.

Confidential business information: Any submissions that contain CBI must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''nonconfidential'' version, and that the CBI is clearly identified by means of brackets. All written submissions, except for CBI, will be made available for inspection by interested persons.

As requested by the Committee, the Commission will not include any CBI in its report. However, all information, including CBI, submitted in this investigation may be disclosed to and used by: (i) the Commission, its employees and offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission, including under 5 U.S.C. Appendix 3; or (ii) U.S. Government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any CBI in a way that would reveal the operations of the firm supplying the information.

Summaries of written submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission on or before July 12, 2024, and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the report'' at the top of the page. The summary may not exceed 500 words and should not include any CBI. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link where the written submission can be found.

By order of the Commission.

Issued: February 29, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–04649 Filed 3–5–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1324]

Importer of Controlled Substances Application: AndersonBrecon Inc. dba PCI Pharma Services

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AndersonBrecon Inc. dba PCI Pharma Services has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 5, 2024. Such persons may also file a written request for a hearing on the application on or before April 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on September 29, 2023, AndersonBrecon Inc. dba PCI Pharma Services, 5775 Logistics Parkway, Rockford, Illinois 61109–3608, applied

to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I
Cocaine	9041	II
Methadone	9250	II

The company plans to import the listed controlled substances for clinical trials. No other activities for these drug codes are authorized for this registration. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04753 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1332]

Importer of Controlled Substances Application: Sigma Aldrich Company LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Sigma Aldrich Company LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 5, 2024. Such persons may also file a written request for a hearing on the application on or before April 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 7, 2024, Sigma Aldrich Company LLC, 3500 Dekalb Street, Saint Louis, Missouri 63118–4103, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methcathinone	1237	I
Mephedrone (4-Methyl-N-methylcathinone).	1248	I
Gamma Hydroxybutyric Acid.	2010	I
Tetrahydrocannabinols	7370	I
4-Bromo-2,5-dimethoxyamphetamine.	7391	I
4-Bromo-2,5-dimethoxyphenethylamine.	7392	I
2,5-Dimethoxyamphetamine.	7396	I
3,4-Methylenedioxyamphetamine.	7400	I
3,4-Methylenedioxy-N-ethylamphetamine.	7404	I
3,4-Methylenedioxymethamphetamine.	7405	I
4-Methoxyamphetamine	7411	I
Dimethyltryptamine	7435	I
N-Benzylpiperazine	7493	I
Heroin	9200	I
Normorphine	9313	I
Amobarbital	2125	II
Secobarbital	2315	II
Nabilone	7379	II
Phencyclidine	7471	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levorphanol	9220	II
Meperidine	9230	II
Thebaine	9333	II
Opium, powdered	9639	II
Levo-alphacetylmethadol	9648	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis. In reference to drug code 7370 (Tetrahydrocannabinols) the company plans to import synthetic Tetrahydrocannabinols. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04756 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1328]

Bulk Manufacturer of Controlled Substances Application: Sterling Pharma USA LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Sterling Pharma USA LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 6, 2024. Such persons may also file a written request for a hearing on the application on or before May 6, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission

of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 9, 2024, Sterling Pharma USA LLC., 10001 Sheldon Drive, Suite 101, Cary, North Carolina 27513, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to manufacture the above-listed controlled substance(s) to support clinical trials. No other activities for these drug codes are authorized for this registration.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04747 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1330]

Bulk Manufacturer of Controlled Substances Application: Stepan Company

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Stepan Company has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 6, 2024. Such persons may also file a written request for a hearing on the application on or before May 6, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 26, 2024, Stepan Company, 100 West Hunter Avenue, Maywood, New Jersey 07607–1021, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cocaine	9041	II
Ecgonine	9180	II

The company plans to bulk manufacture the listed controlled substances for use as internal intermediates or for sale to its customers. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04754 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1047]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Nusachi Labs, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 6, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.''

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on June 13, 2022, Nusachi Labs, LLC, 2909 Armory Drive, Nashville, Tennessee 37204, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04743 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1336]

Importer of Controlled Substances Application: Benuvia Operations, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 5, 2024. Such persons may also file a written request for a hearing on the application on or before April 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 6, 2024, Benuvia Operations, LLC, 3950 North Mays Street, Round Rock, Texas 78665–2729, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Psilocyn	7438	I

The company plans to import the listed controlled substances for clinical trial manufacturing and analytical purposes. sale to research facilities for drug testing and analysis. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04757 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1331]

Bulk Manufacturer of Controlled Substances Application: Organic Consultants LLC DBA Cascade Chemistry

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Organic Consultants LLC DBA Cascade Chemistry has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 6, 2024. Such persons may also file a written request for a hearing on the application on or before May 6, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 24, 2024, Organic Consultants LLC DBA Cascade Chemistry, 90 North Polk Street, Suite 200, Eugene, Oregon 97402–4109, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Meperidine	9230	II
Meperidine intermediate-A	9232	II

Controlled substance	Drug code	Schedule
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Thebaine	9330	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to bulk manufacture small quantities of the listed controlled substances for internal use or for sale as analytical reference standard materials to its customers. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–04755 Filed 3–5–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employment Navigator Data Collection and Matching

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Veterans' Employment and Training Service (VETS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before April 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Wilson Vadukumcherry by telephone at 202–693–0110, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The information collections under OMB Control No. 1293–0016 provides to place job assistance counselors (Employment Navigators) on select military bases to assist transitioning service members move into the civilian labor force. Employment Navigators will assist transitioning service members to get placed on a best-fit pathway for his/her desired career. In order to create return on investment metrics, data must be collected on the services provided by Employment Navigators, and employment-based outcomes that follow. Data is expected to be collected directly from Employment Navigators assisting transitioning service members, as well as any DOL-approved service partners who also provided job-assistance services to the service members. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 21, 2023 (88 FR 88418).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–VETS.

Title of Collection: Employment Navigator Data Collection and Matching.

OMB Control Number: 1293–0016.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 22,550.

Total Estimated Number of Responses: 22,550.

Total Estimated Annual Time Burden: 6,885 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Wilson Vadukumcherry,

Senior PRA Analyst.

[FR Doc. 2024–04679 Filed 3–5–24; 8:45 am]

BILLING CODE 4510–79–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0010]

Fire Protection in Shipyard Employment Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Fire Protection in Shipyard Employment Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by May 6, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the websites. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA

docket number (OSHA–2011–0010) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The Fire Protection in Shipyard Employment Standard specifies a number of information collection requirements. In general, the standard requires employers to develop a written fire safety plan covering elements that identify the potential fire risk hazards and procedures for reporting these hazards, employers to create, maintain, and update a written policy that describes the internal and outside fire response organizations that the employer will use, and employers to notify employees and take the necessary precautions to make sure employees are safe from fire if for any reason a fire extinguishing system stops working. The standard also requires the employer to obtain medical exams for certain workers and to create and maintain records to certify that employees have been made aware of the details of the fire safety plan and that employees have been trained as required by the standard.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements specified in the Fire Protection in Shipyard Employment Standard. The agency is requesting an adjustment decrease in burden from 16,251 to 15,972 hours, a difference of 279 hours. This decrease in burden is due to the decrease in the number of affected workers and in the number of establishments.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Fire Protection in Shipyard Employment Standard.

OMB Control Number: 1218–0248.

Affected Public: Business or other for-profits.

Number of Respondents: 489.

Number of Responses: 185,473.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 15,744.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; or (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at 202–693–1648. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (OSHA–2011–0010). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submission, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC, on February 28, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–04682 Filed 3–5–24; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL CREDIT UNION ADMINISTRATION

Renewals of Agency Information Collections for Comments Request: Proposed Collections

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comments.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Written comments should be received on or before May 6, 2024 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Mahala Vixamar, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314, Suite 5067; Fax No. 703–519–8579; or Email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Mahala Vixamar at (703) 718–1155.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0133.

Title: Investment and Deposit Activities, 12 CFR part 703.

Type of Review: Extension of a previously approved collection.

Abstract: The National Credit Union Administration (NCUA) Federal Credit Union Act, 12 U.S.C. 1757(7), 1757(8), 1757(15), lists securities, deposits, and other obligations in which a Federal Credit Union (FCU) may invest. The regulations related to these areas are contained in Part 703 and Section 721.3 of the NCUA Rules and Regulations, which set forth requirements related to maintaining an adequate investment program. The information collected is used by the NCUA to determine compliance with the appropriate sections of the NCUA Rules and Regulations and FCU Act, which governs investment and deposit activities on the basis of safety and soundness concerns. It is used to determine the level of risk that exists within a credit union, the actions taken by the credit union to mitigate such risk, and helps prevent losses to federal credit unions and the National Credit Union Share Insurance Fund (NCUSIF).

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 54,501.

OMB Number: 3133–0190.

Title: Loans in Areas Having Special Flood Hazards, 12 CFR 760.

Type of Review: Extension of a previously approved collection.

Abstract: This collection of information is set forth in NCUA regulations at 12 CFR part 760 and is required by the National Flood Insurance Reform Act of 1994's amendments to the National Flood Insurance Act of 1968 and the Flood Disaster Protection Act of 1973 (Flood Act). The collection of information pertains to loans secured by buildings and mobile homes located or to be located in areas determined by the Director of the Federal Emergency Management Agency (FEMA) to have special flood hazards.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 185,213.

OMB Number: 3133–0195.

Title: Minority Depository Institution Preservation Program.

Type of Review: Extension of a previously approved collection.

Abstract: Dodd Frank Act amended sec. 308 of the FIRREA to require NCUA, Office of the Comptroller of Currency, and the Federal Reserve Board to establish a program to comply with its goals to preserve and encourage Minority Depository Institutions (MDIs). The NCUA Board issued Interpretive Ruling and Policy Statement (IRPS) 13–1 establishing a MDI preservation program to comply with FIRREA § 308 goals. The IRPS identifies the procedure for a federally insured credit union to determine and document its ability to designate itself as a MDI, resulting in the ability to participate in the Program.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 38.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2024–04688 Filed 3–5–24; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Council on the Humanities will meet to advise the Chair of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out her functions; to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 and make recommendations thereon to the Chair; and to consider gifts offered to NEH and make recommendations thereon to the Chair.

DATES: The meeting will be held on Thursday, March 14, 2024, from 1 p.m. until 4:30 p.m., and Friday, March 15, 2024, from 1 p.m. until adjourned.

ADDRESSES: The meeting will be held by videoconference originating at Constitution Center, 400 7th Street SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, 4th Floor, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The National Council on the Humanities is meeting pursuant to the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended).

The following Committees of the National Council on the Humanities will convene by videoconference on March 14, 2024, from 1 p.m. until 3:20 p.m., to discuss specific grant

applications and programs before the Council:

Research Programs; Preservation and Access; Education Programs; Public Programs; Digital Humanities; Data and Evaluation; Challenge Programs; and Federal/State Partnership.

The National Council will then convene in executive session by videoconference on March 14, 2024, from 3:30 p.m. until 4:30 p.m.

The plenary session of the National Council on the Humanities will convene by videoconference on March 15, 2024, at 1 p.m. The agenda for the plenary session will be as follows:

A. Minutes of Previous Meeting
B. Reports
   1. Farewell Remarks from Former Council member
   2. Chair's Remarks
   3. Updates from Divisions and Offices
   4. Actions on Requests for Chair's Grants and Supplemental Funding
   5. Actions on Previously Considered Applications
C. Research Programs
D. Preservation and Access
E. Education Programs
F. Public Programs
G. Digital Humanities
H. Data and Evaluation
I. Challenge Programs
J. Federal/State Partnership

This meeting of the National Council on the Humanities will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6), and 552b(c)(9)(B) of title 5 U.S.C., as amended, because it will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chair's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: March 1, 2024.

Jessica Graves,

Paralegal Specialist,National Endowment for the Humanities.

[FR Doc. 2024–04721 Filed 3–5–24; 8:45 am]

BILLING CODE 7536–01–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

Notice of Meeting: National Intelligence University Board of Visitors

AGENCY: National Intelligence University (NIU), Office of the Director of National Intelligence (ODNI).

ACTION: Notice of Federal Advisory Committee meeting of the National Intelligence University Board of Visitors.

SUMMARY: ODNI is publishing this notice to announce that the following Federal Advisory Committee meeting of the NIU Board of Visitors (BoV) will take place. This meeting is closed to the public.

DATES: Thursday, 28 March, 8:30 a.m. to 5 p.m., Bethesda, MD.

ADDRESSES: National Intelligence University, 4600 Sangamore Road, Bethesda, MD 20816.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia ''Patty'' Larsen, Designated Federal Officer, (301) 243–2118 (Voice), *excom@odni.gov* (email). Mailing address is National Intelligence University, Roberdeau Hall, Washington, DC 20511. Website: *http://ni-u.edu/wp/about-niu/leadership-2/board-of-visitors/.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. 1001–1014), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150. The meeting includes the discussion of classified information and classified materials regarding intelligence education issues, internal personnel rules and practices of NIU, and pre-decisional strategic planning matters; and the Director of National Intelligence, or her designee, in consultation with the ODNI Office of General Counsel, has determined the meeting will be closed to the public under the exemptions set forth in 5 U.S.C. 552b(c)(1),552b(c)(2), and 552b(c)(9)(B).

I. Purpose of the Meeting: The Board will discuss and provide written observations and recommendations on matters relating to NIU personnel, budget, facilities, strategic planning, information technology, intelligence programs, and whole of institution assessment data, as well as discuss current classified intelligence education issues.

II. Agenda: Welcome and Call to Order; Opening Remarks; Strategic Planning; Resources—Assessments; Break for Lunch; Visioning Session; Resources—Budget, Information Technology, Personnel, Whole of Institution Assessment Data.

III. Meeting Accessibility: The public or interested organizations may submit written statements to the NIU BoV about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of a planned meeting of the NIU BoV.

IV. Written Statements: All written statements shall be submitted to the Designated Federal Officer for the NIU BoV, and this individual will ensure that the written statements are provided to the membership for their consideration.

Robert A. Newton,

Committee Management Officer and Deputy Chief Operating Officer.

[FR Doc. 2024–04732 Filed 3–5–24; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0001]

Sunshine Act Meetings

TIME AND DATE: Week of March 4, 2024.

PLACE: Via Teleconference.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Week of March 4, 2024

Thursday, March 7, 2024

9:45 a.m. Affirmation Session (Public Meeting) (Tentative). Florida Power & Light Co. (Turkey Point Nuclear Generating Units 3 and 4), Licensing Board's Certified Question on Timing of Issuance of Notice of Opportunity For Hearing (Tentative) (Contact: Wesley Held: 301–287–3591)

Additional Information: By a vote of 4–0 on March 1, 2024, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 that this item be affirmed with less than one week notice to the public. The item will be affirmed in the meeting being held on March 7, 2024. The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode at *https://www.nrc.gov/pmns/mtg.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or

need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: March 1, 2024.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2024–04815 Filed 3–4–24; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–0320; NRC–2024–0050]

Draft Programmatic Agreement: TMI–2SOLUTIONS, LLC; Three Mile Island Nuclear Station, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comment on a draft Programmatic Agreement (PA) between the NRC, Pennsylvania State Historic Preservation Office (SHPO), and TMI–2 Energy Solutions (TMI–2*Solutions*). The purpose of this draft PA is to resolve any adverse effects to historic properties identified during consultation for a license amendment request for the Three Mile Island Nuclear Station, Unit No. 2 (TMI–2), located in Londonderry Township, Dauphin County, Pennsylvania. TMI–2*Solutions* will be engaging in certain major decommissioning activities, including the physical demolition of buildings previously deemed eligible for the National Register of Historic Places (NRHP). Because the impacts on the historic properties from these decommissioning activities have not been previously evaluated and are not bounded by NUREG–0586, ''Final Generic Environmental Impact Statement (GEIS) on Decommissioning of Nuclear Facilities'', the NRC initiated consultation under the National Historic Preservation Act (NHPA). During the NHPA section 106 consultation, it was determined that there would be adverse effects to historic properties and a PA was developed to address resolution of adverse effects.

DATES: Submit comments by April 5, 2024. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0050. Address questions about Docket IDs to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.
- *Email comments to: TMI2Environmental@nrc.gov.*

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jean Trefethen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0867; email: *Jean.Trefethen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2024–0050 when contacting the NRC about the availability of information regarding this action. You may obtain publicly available information related to this action by the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0050.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *Project Website:* Information related to the TMI–2 project can be accessed on NRC's TMI–2 public website at *https://www.nrc.gov/info-finder/decommissioning/power-reactor/three-mile-island-unit-2.html,* under the section titled ''2.0 Site Status Summary,'' scroll down to ''Environmental Review of Cultural and Historic Resource Impacts from Decommissioning Activities'' and click on draft Programmatic Agreement, Draft Report for Comment.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2024–0050 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment

submissions available to the public or entering the comment into ADAMS.

II. Discussion

By letter dated February 22, 2023 (ADAMS Accession No. ML23058A064), TMI–2*Solutions* requested an amendment to Possession Only License No. DPR–73. TMI–2*Solutions* will be engaging in certain major decommissioning activities, including the physical demolition of buildings previously deemed eligible for the National Register of Historic Places (NRHP). Paragraph 50.82(a)(6)(ii) of title 10 of the *Code of Federal Regulations* (10 CFR) states that licensees shall not perform any decommissioning activities that would result in significant environmental impacts that have not been previously reviewed. Adverse impacts, such as certain alterations or demolition to structures that have been deemed eligible for listing on the NRHP, could be considered unreviewed significant environmental impacts under 10 CFR 50.82(a)(6)(ii). Because the impacts on the historic properties from TMI–2*Solutions'* proposed decommissioning activities have not been previously evaluated, TMI–2*Solutions* requested an amendment to evaluate the impacts of the decommissioning activities on the NRHP-eligible properties.

The NRC uses its National Environmental Policy Act process for developing environmental assessments (EAs) to facilitate consultation under section 106 of the National Historic Preservation Act (NHPA), pursuant to 36 CFR 800.8.

The NRC met with the Advisory Council on Historic Preservation, the Pennsylvania State Historic Preservation Officer (SHPO), TMI–2*Solutions,* and other consulting parties to discuss how to address the adverse effects to historic properties. The parties agreed to develop a PA to resolve any adverse effects. As explained in the PA, once the agreement is executed, the NRC will become the lead agency for implementation of the PA.

The draft PA addresses the potential direct and indirect adverse effects from the decommissioning activities and ensures that appropriate mitigation measures are implemented. The NRC's final EA will include the final PA and therefore conclude NHPA section 106 consultation.

III. Request for Public Comment

The NRC is requesting public comment on the draft PA. The NRC will consider these comments before finalizing the PA, which will be published as an appendix in the final EA. The draft PA is available in ADAMS under Accession No. ML24044A184.

Dated: March 1, 2024.

For the Nuclear Regulatory Commission.

Robert Sun,

Chief, Environmental Project Management Branch 2, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–04768 Filed 3–5–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–198 and CP2024–204]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 8, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–198 and CP2024–204; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 196 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* February 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Arif Hafiz; *Comments Due:* March 8, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–04759 Filed 3–5–24; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

In accordance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Statement Regarding Contributions and Support; OMB 3220–0099.

Under section 2 of the Railroad Retirement Act (45 U.S.C. 231a), dependency on an employee for one-half support at the time of the employee's death can affect (1) entitlement to a survivor annuity when the survivor is a parent of the deceased employee; (2) the amount of spouse and survivor annuities; and (3) the Tier II restored amount payable to a widow(er) whose annuity was reduced for receipt of an employee annuity, and who was dependent on the railroad employee in the year prior to the employee's death. One-half support may also negate the public service pension offset in Tier I for a spouse or widow(er). The Railroad Retirement Board (RRB) utilizes Form G–134, Statement Regarding Contributions and Support, to secure information needed to adequately determine if the applicant meets the one-half support requirement. One response is completed by each respondent. Completion is required to obtain benefits. The RRB proposes a minor editorial changes to Form G–134 to change the date under section 1 ''General Instructions''.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–134			
With Assistance	11	147	27
Without assistance	4	180	12
Total	15		39

2. Title and purpose of information collection: Financial Disclosure Statement; OMB 3220–0127.

Under section 10 of the Railroad Retirement Act and section 2(d) of the Railroad Unemployment Insurance Act (45 U.S.C. 231i), the RRB may recover overpayments of annuities, pensions, death benefits, unemployment benefits, and sickness benefits that were made erroneously. An overpayment may be waived if the beneficiary was not at fault in causing the overpayment and recovery would cause financial hardship. The regulations for the recovery and waiver of erroneous payments are contained in 20 CFR 255 and CFR 340.

The RRB utilizes Form DR–423, Financial Disclosure Statement, to obtain information about the overpaid beneficiary's income, debts, and expenses if that person indicates that (s)he cannot make restitution for the overpayment. The information is used to determine if the overpayment should be waived as wholly or partially uncollectible. If waiver is denied, the information is used to determine the size and frequency of installment payments. The beneficiary is made aware of the overpayment by letter and is offered a variety of methods for recovery. One response is requested of each respondent. Completion is voluntary. However, failure to provide the requested information may result in a denial of the waiver request. The RRB proposes no changes to Form DR–423.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
DR–423	1,200	85	1,700

3. Title and purpose of information collection: collection: Representative Payee Monitoring; OMB 3220–0151.

Under section 12 of the Railroad Retirement Act (RRA) (45 U.S.C. 231k), the RRB may pay annuity benefits to a representative payee when an employee, spouse, or survivor annuitant is incompetent or a minor. The RRB is responsible for determining if direct payment to an annuitant or a representative payee would best serve the annuitant's best interest. The accountability requirements authorizing the RRB to conduct periodic monitoring of representative payees, including a written accounting of benefit payments received, are prescribed in 20 CFR 266.7. The RRB utilizes the following forms to conduct its representative payee monitoring program.

Form G–99a, *Representative Payee Report,* is used to obtain information needed to determine whether the benefit payments certified to the representative payee have been used for the annuitant's current maintenance and personal needs and whether the representative payee continues to be concerned with the annuitant's welfare. RRB Form G–99c, *Representative Payee Evaluation Report,* is used to obtain more detailed information from a representative payee who fails to complete and return Form G–99a or in situations when the returned Form G–99a indicates the possible misuse of funds by the representative payee. Form G–99c contains specific questions concerning the representative payee's performance and is used by the RRB to determine whether or not the representative payee should continue in that capacity. The RRB proposes no changes to Form G–99a or Form G–99c.

Form G–106, *Statement of Care and Responsibility to Annuitant* is used in cases where the representative payee does not have custody of the annuitant. Form G–106 is used to solicit information about the representative

payee's performance and the annuitant's well-being from the custodian of the annuitant. The form contains specific questions concerning the representative payee's performance and is used by the RRB to determine whether or not the representative payee should continue in that capacity. Completion of the forms in this collection is required to retain benefits.

The RRB proposes the following changes for Form G–106:

- Add a drop-down box 'Second Request' at the top of the form to when the RRB needs to follow-up with a Third-Party Custodian who did not respond to the initial request.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–99a (legal and all other, excepting parent for child)	5,300	18	1,590
G–99c (Parts I and II)	300	24	120
G–99c (Parts I, II, and III)	120	31	62
G–106	500	10	83
Total	6,220		1,855

4. Title and purpose of information collection: Earnings Information Request; OMB 3220–0184.

Under section 2 of the Railroad Retirement Act (45 U.S.C. 231a), an annuity is not payable, or is reduced for any month(s) in which the beneficiary works for a railroad or earns more than prescribed amounts. The provisions relating to the reduction or non-payment of annuities by reason of work are prescribed in 20 CFR 230.

The RRB utilizes Form G–19–F, *Earnings Information Request,* to obtain earnings information that either had not been previously reported or erroneously reported by a beneficiary. Currently the claimant is asked to enter the date they stopped working, if applicable. If a respondent fails to complete the form, the RRB may be unable to pay them benefits. One response is requested of each respondent. The RRB proposes no changes to the Form G–19–F.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–19–F	700	8	93
Total	700		93

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Kennisha Money at (312) 469–2591 or *Kennisha.Money@rrb.gov.* Comments regarding the information collection should be addressed to Brian Foster, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–1275 or emailed to *Brian.Foster@rrb.gov.* Written comments should be received within 60 days of this notice.

Brian Foster,

Clearance Officer.

[FR Doc. 2024–04725 Filed 3–5–24; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99643; File No. SR–BX–2024–007]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2024, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program

where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2010,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above, the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

[3] *See* Securities Exchange Act Release No. 34–62396 (June 28, 2010), 75 FR 38585 (July 2, 2010) (SR–BX–2010–012).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW.

[6] *See* Securities Exchange Act Release No. 34–62396 (June 28, 2010), 75 FR 38585 (July 2, 2010) (SR–BX–2010–012).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange is currently working to expand the amount of power and number of cabinets available in colocation.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–BX–2024–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BX–2024–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BX–2024–007 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04700 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99640; File No. SR–FINRA–2024–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Amend FINRA Rule 6730 (Transaction Reporting) To Reduce the 15-Minute TRACE Reporting Timeframe to One Minute

February 29, 2024.

On January 11, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change to amend FINRA Rule 6730 to reduce the 15-minute TRACE reporting timeframe to one minute, with exceptions for member firms with de minimis reporting activity and for manual trades. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period for Commission action. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the comments received. Accordingly, pursuant to section 19(b)(2) of the Act, the Commission designates April 24, 2024, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–FINRA–2024–004).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[5]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04697 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

[3] *See* Securities Exchange Act Release No. 99404 (January 19, 2024), 89 FR 5034 (January 25, 2024). Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-finra-2024-004/srfinra2024004.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99641; File No. SR–OCC–2024–003]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Concerning the Option Clearing Corporation's Interpretative Guidance on Contract Adjustments for Cash Dividends and Distributions

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 20, 2024, The Options Clearing Corporation (''OCC'' or ''Corporation'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)(i) [3] of the Act and Rule 19b–4(f)(1) [4] thereunder, such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change would re-issue interpretative guidance relating to the adjustment of stock options for cash dividends and distributions on underlying securities with certain amendments, including (1) to reflect previously approved changes in the process for making such adjustment determinations; and (2) to address OCC's general approach to certain additional scenarios. Amendments to the interpretative guidance, are included in Exhibit 5 of File No. SR–OCC–2024–003. Material proposed to be added is marked by underlining, and material proposed to be deleted is marked with strikethrough text. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the By-Laws and Rules.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

OCC is the issuer of and sole clearing agency for standardized equity options listed on national securities exchanges registered with the Commission. In accordance with OCC's By-Laws, adjustments may be made to some of the standardized terms of outstanding options upon the occurrence of certain events related to the underlying security, such as a stock dividend, stock distribution, stock split, reverse stock split, rights offering, distribution, reorganization, recapitalization, reclassification in respect of an underlying security, or a merger, consolidation, dissolution or liquidation of the issuer of the underlying security.[6] The determination whether to adjust outstanding options in response to a particular event, and, if so, what the adjustment should be, is made by OCC, taking into consideration policies and interpretations established in OCC's By-Laws and any policies and interpretations having general application to specific types of events or specified kinds of cleared contracts established by a committee (the ''Securities Committee'') consisting of representatives of each of the U.S. options markets and a representative of OCC.[7]

OCC previously filed with the Commission and issued interpretative guidance concerning the application of OCC's adjustment policies and procedures and other adjustment rules

[6] Adjustments for listed options are discussed at length in the Characteristics and Risks of Standardized Options (''Options Disclosure Document'' or ''ODD''), which broker-dealers are required to provide to a customer prior to accepting an order to purchase or sell a listed option. *See* 17 CFR 240.9b–1. The Options Disclosure Document is also available on OCC's website: *https://www.theocc.com/company-information/documents-and-archives/options-disclosure-document.*

[7] *See* OCC By-Laws, Art. VI § 11.

for cash dividends.[8] In the interest of promoting clarity and transparency for market participants, OCC is proposing to re-issue that interpretative guidance subject to proposed amendments that would (1) update the interpretative guidance's discussion of how adjustment determinations are made to reflect subsequent changes to the determination process since the interpretative guidance was last issued, and (2) provide additional guidance on certain underlying events.[9] OCC does not propose to change its policies or practices with respect to such contract adjustments. OCC merely proposes to publish guidance reflecting its current policies and practices. Accordingly, OCC does not believe that this proposed change would have any impact on market participants other than to provide them with additional information.

(1) Purpose

Background

OCC's By-Laws and Rules authorize OCC to make adjustments to listed options when certain events occur related to the underlying security, such as a stock dividend, stock distribution, stock split, reverse stock split, rights offering, distribution, reorganization, recapitalization, or reclassification with respect to the underlying security or the merger, consolidation, dissolution or liquidation of the issuer of the underlying security. The By-Laws provide policies and procedures for making such determinations, including that OCC determines whether to adjust a contract, taking into account such factors as fairness to holders and writers (or purchasers and sellers) of the affected contracts, the maintenance of a fair and orderly market in the affected contracts, consistency of interpretation and practice, efficiency of exercise settlement procedures, and the coordination with other clearing agencies of the clearance and settlement of transactions in the underlying interest.[10] OCC applies these factors to a particular corporate action on a case-by-case basis, considering the circumstances known to it at the time the determination is made, subject to OCC's discretion to depart from policy and precedent when the Corporation determines that unusual circumstances make such a departure appropriate.[11]

OCC's By-Laws also provide general rules applicable to specific types of corporate actions, including with respect to cash dividends or distributions made by the issuer of an underlying security. For example, the By-Laws establish a general rule that OCC does not adjust listed options to reflect ''ordinary cash dividends or distributions,'' which the By-Laws define to mean ''[c]ash dividends or distributions (regardless of size) by the issuer of the underlying security which [OCC] believes to have been declared pursuant to a policy or practice of paying such dividends or distributions on a quarterly or other regular basis or which [OCC] believes represents an acceleration or deferral of such payments.'' [12] OCC established this general rule because when an issuer's policy or practice of paying such dividends is public, such ordinary dividends can be priced into options premiums.[13] OCC's By-Laws also provide that for cash dividends not declared pursuant to an issuer's policy or practice of paying such distributions at regular intervals (*i.e.,* ''special'' cash dividends and distributions), OCC will not adjust if the amount distributed is less than $0.125 per share (or $12.50 per contract for listed options with a unit of trading larger than 100 shares). OCC established this de minimis threshold in part to avoid the proliferation of outstanding option symbols and series.[14]

In connection with the adoption of the general rules against adjustments for cash dividends and distributions that are ordinary or below the de minimis threshold, OCC previously filed and published interpretative guidance promulgated by its Securities Committee to address questions about how those rules would be administered and applied.[15] Presented in question and answer (''Q&A'') format, the interpretative guidance provided an overview of OCC's adjustment policies with respect to cash dividends and guidance on the application of those policies in a variety of scenarios. OCC has since updated and re-issued that interpretative guidance, the last time in 2012.[16] Based on its continued relevance to market participants seeking to understand how OCC applies its adjustment policies, OCC proposes to re-issue the interpretative guidance with certain updates discussed below.

(1) Conforming Changes To Reflect the Current Determination Process

The proposed changes would remove references to the adjustment panel of the Securities Committee in the interpretative guidance's discussion of how options adjustments are made. Since the interpretative guidance was last issued in 2012, the Commission approved a proposed rule change that affected the determination process.[17] Previously, an adjustment panel of the Securities Committee, consisting of representatives from the exchanges on which an option was listed and OCC's Chairman, would make determinations about whether that option should be adjusted in response to a corporate action. Currently, adjustment determinations are made by OCC rather than adjustment panels of the Securities Committee.[18] However, the Securities Committee still maintains a role in promulgating statements of policy and interpretations having general

[8] *See, e.g.,* Exchange Act Release No. 68531 (Dec. 21, 2012), 77 FR 77157 (Dec. 31, 2012) (SR–OCC–2012–26).

[9] Consistent with prior practice, the interpretative guidance would be issued as an OCC Information Memorandum that would supersede the previously published Information Memoranda related to this interpretative guidance. The Information Memorandum would contain prefatory material intended to provide context for its issuance, remind readers of its relationship to the prior Information Memoranda and this proposed rule change, and summarize the relevant OCC By-Laws that are the subject of the interpretation. OCC does not believe this prefatory material is a rule within the meaning of Section 19(b) of the Exchange Act, 15 U.S.C. 78s(b), and the regulations thereunder because unlike the interpretative guidance promulgated through this proposed rule change, the prefatory material it is not a stated policy, practice or interpretation that establishes or changes any standard, limit, or guideline with respect to the rights, obligations or privileges of specified persons or the meaning, administration, or enforcement of an existing rule. *See* 17 CFR 240.19b–4(a)(6)(ii). Nor does the prefatory material constitute a material aspect of the operation of OCC. *See* 17 CFR 240.19b–4(a)(6)(i). OCC is providing a copy of the Information Memorandum it intends to issue upon implementation of the new guidance as Exhibit 3 to File No. SR–OCC–2024–003.

[10] *See* OCC By-Laws, Art. VI § 11(a).

[11] *Id.*

[12] See OCC By-Laws, Art. VI § 11A, Interpretation and Policy .01.

[13] *See* Exchange Act Release No. 55258 (Feb 8, 2007), 72 FR 7701, 7703 (Feb. 16, 2007) (SR–OCC–2006–01).

[14] Symbols can proliferate when a dividend amount is added to the deliverable, yielding a non-standard option. *Id.,* at note 14 and accompanying text. The resulting non-standard options may be illiquid and difficult to trade. Following an adjustment, exchanges typically introduce standard options with the same strikes.

[15] *See* Exchange Act Release No. 58059 (June 30, 2008), 73 FR 39367 (July 9, 2008) (SR–OCC–2008–10).

[16] *See* Exchange Act Release No. 68531, *supra* note 6 [sic]. *See also* Exchange Act Release No. 66742 (Apr. 5, 2012), 77 FR 21819 (Apr. 11, 2012) (SR–OCC–2012–05); Exchange Act Release No. 59442 (Feb. 24, 2009), 74 FR 9654 (Mar. 5, 2009) (SR–OCC–2009–01).

[17] *See* Exchange Act Release No. 69977 (July 11, 2013), 78 FR 42815 (July 17, 2013) (SR–OCC–2013–05).

[18] This change in governance arose from a request by the options exchanges promoted by a desire to consider ways to lessen investor confusion and enhance consistency in making option contract adjustments. *See* Exchange Act Release No. 69642 (May 28, 2013), 78 FR 33138, 33139 (June 3, 2013) (SR–OCC–2013–05).

application to specified types of corporate actions or specified kinds of cleared contracts.[19] In making adjustment determinations, OCC must consider such policy statements and interpretations in addition to the factors and general rules set forth in the By-Laws in light of the circumstances known to OCC at the time such determination is made, subject to OCC's discretion to depart from policy or precedent when the OCC determines that unusual circumstances make such a departure appropriate.[20] OCC assumed sole responsibility for making adjustment determinations after corresponding updates to the Options Disclosure Document were approved by the Commission in 2018.[21] Accordingly, when OCC re-issues the interpretative guidance on cash dividends and distributions, OCC proposes to replace references to determinations made by an adjustment panel of the Securities Committee with references to OCC and make other non-substantive, textual edits to the interpretative guidance consistent with that change. These changes are intended to reflect the current, Commission-approved process for adjustment determinations made by OCC.

(2) Additional Interpretative Guidance

OCC also proposes to add additional Q&As that would provide guidance for several situations OCC has observed since the interpretative guidance was last issued, including (a) specific guidance with respect to variable dividends, and (b) additional guidance with respect to dividends issued by real estate investment trusts (''REITs'').

a. Variable Dividends

OCC has seen an increase in the number of issuers that have established policies or practices of distributing ''variable dividends.'' Typically, such variable dividends are paid at regular intervals if issuer-defined thresholds for paying the dividends are met. The amount of the variable dividend may increase or decrease (sometimes significantly) from dividend to dividend based on issuer-established thresholds and, on occasion, may not be paid at all if the issuer-established thresholds are not met. These variable dividends may also be in addition to regular dividends paid pursuant to the issuer's policy or practice.

For example, on May 19, 2022, Arch Resources, Inc. (ARCH) announced an $8.11 quarterly dividend, which included a fixed component of $0.25 and a variable component of $7.86 per share. In making its adjustment determination, OCC considered an ARCH press release, issued on February 15, 2022, communicating that ARCH was launching a capital return program pursuant to which it planned to ''return to stockholders approximately 50 percent of the prior quarter's discretionary cash flow . . . via a variable quarterly cash dividend in conjunction with its existing fixed quarterly cash dividend.'' [22] OCC determined that the quarterly variable dividend was an ''ordinary dividend'' as defined in Interpretation and Policy .01 to Article VI, Section 11A of OCC's By-Laws, and therefore not subject to adjustment, because the dividend had been declared pursuant to a policy or practice of paying such dividend on a quarterly or other regular basis.[23]

As another example, on March 9, 2022, Zim Integrated Shipping Services Ltd. (ZIM) announced a cash dividend of $17.00 per share, representing 50% of ZIM's 2021 net income, taking into account the quarterly dividends paid during the first three fiscal quarters of the year.[24] Pursuant to the issuer's stated policy, ZIM intended to ''distribute a dividend to shareholders on a quarterly basis at a rate of approximately 20% of the net income derived during such fiscal quarter with respect to the first three fiscal quarters of the year'' and that the ''cumulative annual dividend amount to be distributed by [ZIM] (including the interim dividends paid during the first three fiscal quarters of the year) [would] total 30–50% of the annual net income.'' [25] OCC determined that the $17 dividend was an ''ordinary dividend'' declared pursuant to a policy or practice of paying such dividend on a quarterly or other regular basis, and therefore not subject to adjustment.[26]

OCC proposes to add a Q&A to the interpretative guidance reflecting that if OCC determines such variable dividends are paid pursuant to an issuer's policy or practice of paying such variable dividends at regular intervals, OCC generally considers them to be ordinary dividends and not adjustable, even if, on occasion, no variable dividend is paid or if the amount of the dividend increases or decreases based on the issuer-established thresholds. OCC believes this guidance would align with the precedent described above and provide market participants with greater clarity about how OCC applies the adjustment policies outlined in the By-Laws to variable dividends.

b. REITs

OCC proposes to add further guidance about situations in which an issuer may pay a dividend outside of its normal schedule of dividend payments that the issuer describes as necessary to maintain its tax status as a particular type of organization, such as a REIT. The existing interpretative guidance answered several questions concerning dividends paid by REITs and similar companies. For example, the existing interpretative guidance addressed that while REITs may pay dividends at irregular intervals, these companies often have regular dividend policies, but will actually pay dividends only when certain conditions are met, or in response to market conditions. Similar to the variable dividend situation, in which, on occasion, no variable dividend is paid if issuer-established thresholds are not met, the prior interpretative guidance provided that such REIT distributions generally would be considered ordinary distributions when they occur pursuant to the policy of the company.

However, OCC has observed at least one case in which an issuer has declared a dividend outside of its normal schedule of dividend payments to maintain its tax status as a particular type of organization, such as a REIT. Specifically, On July 22, 2022, Public Storage (''PSA'') announced a ''special,'' ''one-time'' dividend of $13.15 per common share.[27] As explained in the issuer's press release, PSA was distributing a projected tax gain in connection with its investment in

[19] *See* OCC By-Laws, Art. VI § 11(a).

[20] *Id.*

[21] *See* Exchange Act Release No. 84565 (Nov. 9, 2018), 83 FR 57778, 57779 (Nov. 16, 2018) (SR–ODD–2018–01).

[22] *See* Arch Resources Reports Fourth Quarter 2021 Results (Feb. 15, 2022), *https://investor.archrsc.com/2022-02-15-Arch-Resources-Reports-Fourth-Quarter-2021-Results.*

[23] *See* Info Memo #50473 (May 20, 2022). OCC does not issue Info Memos notifying market participants that OCC has determined not to adjust options (a ''No-Adjustment'' Info Memo) each time an issuer announces a dividend OCC determines to be ordinary and therefore not subject to adjustment. In general, OCC considers whether a No-Adjustment Info Memo may be warranted based on inquiries made by Clearing Members or others with respect to a particular corporate action.

[24] *See* ZIM Reports Record Financial Results for the Fourth Quarter and Full Year 2021 (March 9, 2022), *https://investors.zim.com/news/news-details/2022/ZIM-Reports-Record-Financial-Results-for-the-Fourth-Quarter-and-Full-Year-2021/default.aspx.*

[25] *Id.*

[26] *See* Info Memo #50158 (March 9, 2022).

[27] *See* Public Storage Announces $2.3 Billion Special Dividend Related to PS Business Parks Merger Consideration (July 22, 2022), *https://investors.publicstorage.com/news-events/press-releases/news-details/2022/Public-Storage-Announces-2.3-Billion-Special-Dividend-Related-to-PS-Business-Parks-Merger-Consideration/default.aspx.*

another company that had been acquired ''in order to meet the distribution requirements as a [REIT].'' [28] Nevertheless, OCC determined that the dividend was non-ordinary under its By-Laws and issued an Info Memo concerning an adjustment to options on PSA.[29]

As OCC would clarify in the further guidance, such a dividend would most likely be considered non-ordinary and warrant an adjustment if OCC determines that the dividend is not being made pursuant to the issuer's established dividend policies and practices based on the company's departure from its regular dividend schedule and any characterization the company may make about the pay-out as ''special'' or ''one time.'' In other words, an issuer's characterization of a dividend as necessary to maintain its tax status as a particular type of organization is not determinative of whether a dividend is ''ordinary'' under OCC's By-Laws. Rather, the question is whether the dividend is paid pursuant to an issuer's policy of paying such a dividend at regular intervals to maintain its tax status. If such an issuer announces a special dividend outside of its regular dividend policies and practices, such dividend will most likely be considered non-ordinary and warrant an adjustment even if the issuer is paying the dividend to maintain its tax status. OCC proposes to add a Q&A to the interpretative guidance to reflect OCC's practices in this situation.

(2) Statutory Basis

OCC believes the proposed rule changes are consistent with Section 17A of the Exchange Act and the rules and regulations thereunder. Section 17A(b)(3)(F) of the Exchange Act [30] requires, among other things, that the rules of a clearing agency be designed to protect investors and the public interest. OCC believes that by allowing it to amend and re-issue the interpretative guidance, the proposed changes would protect investors and the public interest by providing market participants with up-to-date information about OCC's current process for making adjustment determinations. In addition, OCC believes the additional interpretative guidance would provide investors and the general public further clarity about the application of OCC's adjustment policies and procedures to scenarios not specifically addressed in the existing guidance. Providing this information will help investors make more informed decisions in connection with their participation in the listed options market. Accordingly, OCC believes the proposed changes are consistent with Section 17A(b)(3)(F) of the Exchange Act.[31]

In addition, Exchange Act Rule 17Ad–22(e)(23) requires OCC to maintain written policies and procedures reasonably designed to, among other things, publicly disclose all relevant rules and material procedures and provide sufficient information to enable participants to identify and evaluate the risks they incur by participating in OCC.[32] The proposed changes would allow OCC to update interpretative guidance concerning its adjustment policies and procedures previously filed as a rule with the Commission, thereby facilitating the re-issuance of guidance about material procedures that remain relevant. OCC believes that by updating the guidance to reflect current precedent, the proposed changes will help participants in the listed options market to better understand the risks related to contract adjustments in the scenarios addressed, consistent with the requirements of Rule 17Ad–22(e)(23).[33]

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Exchange Act requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[34] The proposed changes would amend interpretative guidance applicable to the adjustment of all listed options issued for a particular underlying security. These proposed changes would not impact the rights or obligations of Clearing Members or other participants in a way that would benefit or disadvantage any participant versus another participant. To the contrary, this proposed change would provide all market participants with information relevant to understanding the risks of participation. Accordingly, OCC does not believe that the proposed changes have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comment on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [35] and paragraph (f) of Rule 19b–4 [36] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.[37]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–OCC–2024–003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–OCC–2024–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

[28] *Id.*

[29] *See* Info Memo #50775 (July 25, 2022).

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] *Id.*

[32] 17 CFR 240.17Ad–22(e)(23)(i), (ii).

[33] 17 CFR 240.17Ad–22(e)(23).

[34] 15 U.S.C. 78q–1(b)(3)(I).

[35] 15 U.S.C. 78s(b)(3)(A).

[36] 17 CFR 240.19b–4(f).

[37] Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Regulation 40.6.

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR–OCC–2024–003 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04698 Filed 3–5–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99647; File No. SR–ISE–2024–07]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2017,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to

[38] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR–NASDAQ–2010–019). In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Cabinet Proximity Option program. *See* Securities Exchange Act Release No. 34–81903 (October 19, 2017), 82 FR 49450 (October 25, 2017) (SR–ISE–2017–91).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW.

[6] *See* Securities Exchange Act Release No. 34–81903 (October 19, 2017), 82 FR 49450 (October 25, 2017) (SR–ISE–2017–91).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above, the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange is currently working to expand the amount of power and number of cabinets available in colocation.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–2024–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2024–07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2024–07 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04704 Filed 3–5–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99635; File No. SR–MEMX–2024–06]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule To Adopt Connectivity and Application Session Fees for MEMX Options

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 15, 2024, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the Fee Schedule to: (i) apply the Exchange's current Connectivity and Application Session fees to MEMX Options Users, and (ii) make an organizational change to its existing fee schedule for the Exchange's pre-existing equities market (''MEMX Equities''), in order to create a separate fee schedule for Connectivity Fees (for both MEMX Equities and MEMX Options). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal immediately. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The Exchange is filing a proposal to amend the Fee Schedule to: (i) apply the Exchange's current Connectivity and Application Session fees to MEMX Options Users, and (ii) make an organizational change to its existing fee schedule for the Exchange's pre-existing equities market (''MEMX Equities''), in order to create a separate fee schedule for Connectivity Fees (for both MEMX Equities and MEMX Options). The Exchange believes that these changes will provide greater transparency to Members about how the Exchange assesses fees, as well as allowing Members to more easily validate their bills on a monthly basis. The Exchange notes that none of these changes amend any existing fee applicable to MEMX Equities. The Exchange is proposing to implement the proposal immediately. The Exchange previously filed the proposal on October 24, 2023 (SR–MEMX–2023–29) (the ''Initial Proposal''). The Exchange withdrew the Initial Proposal and replaced the proposal with SR–MEMX–2023–39 (the ''Second Proposal''). The Exchange recently withdrew the Second Proposal and is replacing it with the current filing (SR–MEMX–2024–06).

As set forth below, the Exchange believes that its proposal provides a great deal of transparency regarding the cost of providing connectivity services and anticipated revenue and that the proposal is consistent with the Act and associated guidance. The Exchange is re-filing this proposal promptly following the withdrawal of the Second Proposal in order to update the Cost Analysis included in the Second Proposal.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(i) Fees for Connectivity to MEMX Options

As noted above, the Exchange is proposing to apply the current fees it charges to Members and non-Members [3] for physical connectivity to the Exchange and for application sessions (otherwise known as ''logical ports'') that a Member utilizes in connection with their participation on the Exchange (together with physical connectivity, collectively referred to in this proposal as ''connectivity services'', as described in greater detail below) to both Users of MEMX Equities and MEMX Options.[4] Specifically, the Exchange will continue to charge $6,000 per month for a physical connection in the data center where the Exchange primarily operates under normal market conditions (''Primary Data Center''), and $3,000 per month for a physical connection at the geographically diverse data center, which is operated for backup and disaster recovery purposes (''Secondary Data Center''). These physical connections can be used to access both platforms, accordingly, a firm that is a Member of both MEMX Equities and MEMX Options may use a single physical connection to access its application sessions at both MEMX Equities and MEMX Options. This differs from application sessions in that a firm that is a Member of both MEMX Equities and MEMX Options would need to purchase separate application sessions for each trading platform in order to access each such trading platform. These application session fees will continue to be $450 per month for an application session used for order entry (''Order Entry Port'') and $450 per month for an application session for receipt of drop copies (''Drop Copy Port''), to the extent such ports are in the Primary Data Center. As is true today for MEMX Equities, the Exchange will not charge for Order Entry Ports or Drop Copy Ports in the Secondary Data Center. The Exchange's proposal to apply the same fees to Equities and Options stems from the same cost analysis it conducted in adopting those fees to its Equities Members,[5] which the Exchange has reviewed and updated for 2024 as detailed below. Given that the Exchange has only recently launched MEMX Options, however, and the fact that its analysis is based on projections across all potential revenue streams, the Exchange is committing to conduct a one-year review after these fees are applied. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs, or to decrease fees in the event that revenue materially exceeds expectations.

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

In proposing to charge fees for connectivity services to MEMX Options, the Exchange has sought to be especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related services, and also carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[6] and Rule 19b–4 thereunder,[7] with respect to the types of information self-regulatory organizations (''SROs'') should provide when filing fee changes, and Section 6(b) of the Act,[8] which requires, among other things, that exchange fees be reasonable and equitably allocated,[9] not designed to permit unfair discrimination,[10] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[11] This rule change proposal addresses those requirements, and the analysis and data in each of the sections that follow are designed to clearly and comprehensively show how they are met.[12]

As detailed below, MEMX calculated its aggregate annual costs for providing physical connectivity to both MEMX Equities and MEMX Options in 2024 at $14,970,454 and its aggregate annual costs for providing application sessions at $7,185,273. In order to cover the aggregate costs of providing connectivity to its Options and Equities Users (both Members and non-Members) going forward and to make a modest profit, as described below, the Exchange is proposing to modify its Fee Schedule, pursuant to MEMX Rules 15.1(a) and (c), to charge a fee to Options Users, as it currently does to Equities Users, of $6,000 per month for each physical connection in the Primary Data Center and of $3,000 per month for each physical connection in the Secondary Data Center. The Exchange also proposes to modify its Fee Schedule, pursuant to MEMX Rules 15.1(a) and (c), to charge a fee to Options Users, as it currently does to Equities Users, of $450 per month for each Order Entry Port and Drop Copy Port in the Exchange's Primary Data Center, as further described below.[13]

Cost Analysis

Background on Cost Analysis

In February 2024, MEMX completed an updated study of its aggregate projected costs to produce market data and connectivity across both its Equities and Options platforms in 2024 (the ''Cost Analysis'').[14] The Cost Analysis required a detailed analysis of MEMX's aggregate baseline costs, including a

[3] Types of market participants that obtain connectivity services from the Exchange but are not Members include service bureaus and extranets. Service bureaus offer technology-based services to other companies for a fee, including order entry services to Members, and thus, may access application sessions on behalf of one or more Members. Extranets offer physical connectivity services to Members and non-Members.

[4] MEMX Options launched on September 27, 2023.

[5] *See* Securities Exchange Act Release No. 59846 (September 27, 2022), 87 FR 59845 (October 3, 2022) (SR–MEMX–2022–026).

[6] 15 U.S.C. 78s(b)(1).

[7] 17 CFR 240.19b–4.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(8).

[12] In 2019, Commission staff published guidance suggesting the types of information that SROs may use to demonstrate that their fee filings comply with the standards of the Exchange Act (''Fee Guidance''). While MEMX understands that the Fee Guidance does not create new legal obligations on SROs, the Fee Guidance is consistent with MEMX's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019) available at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[13] As proposed, fees for connectivity services would be assessed based on each active connectivity service product at the close of business on the first day of each month. If a product is cancelled by a Member's submission of a written request or via the MEMX User Portal prior to such fee being assessed then the Member will not be obligated to pay the applicable product fee. MEMX will not return pro-rated fees even if a product is not used for an entire month.

[14] The updated Cost Analysis completed in February 2024 is based on the same principles applied to the Cost Analysis completed in September 2023 that was included in the Initial Proposal but contains updated figures now that MEMX Options has been operational for several months.

determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services and trading permits, regulatory services, physical connectivity, and application sessions (which provide order entry, cancellation and modification functionality, risk functionality, ability to receive drop copies, and other functionality). MEMX separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers''). Next, MEMX adopted an allocation methodology with various principles to guide how much of a particular cost should be allocated to each core service. For instance, fixed costs that are not driven by client activity (*e.g.,* message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (80%), with smaller allocations to logical ports (11%), and the remainder to the provision of transaction execution, regulatory services, and market data services (9%). In contrast, costs that are driven largely by client activity (*e.g.,* message rates), were not allocated to physical connectivity at all but were allocated primarily to the provision of transaction execution and market data services (80%) with a smaller allocation to application sessions (20%). The allocation methodology was decided through conversations with senior management familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an estimated allocation of each cost driver to each core service, resulting in the cost allocations described below.

By allocating segmented costs to each core service, MEMX was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has four primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below.

Through the Exchange's extensive Cost Analysis, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of connectivity services, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of connectivity services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to network connectivity services. In turn, the Exchange allocated certain costs more to physical connectivity and others to application sessions, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, MEMX estimates that the cost drivers to provide connectivity services in 2024, including both physical connections and application sessions, will result in an aggregate annual cost of $22,155,727, as further detailed below. The Exchange notes that it utilized the same principles to generate the 2021 Cost Analysis, applicable to Equities only, and at that time, the estimated annual aggregate cost to provide connectivity services was $13,724,580. The differences between such estimated costs and the overall analysis are primarily based on: (1) the addition of MEMX Options, (ii) increased, and in some cases decreased, costs projected by the Exchange, (iii) and changes made to reallocate certain costs into categories that more closely align the Exchange's audited financial statements, as further described below.

Costs Related To Offering Physical Connectivity

The following chart details the individual line-item costs considered by MEMX to be related to offering physical connectivity as well as the percentage of the Exchange's overall costs such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 18% of its overall Human Resources cost to offering physical connectivity).

COSTS DRIVER	COSTS	% of ALL
Human Resources	$ 6,374,100	18%
Connectivity	$ 732,216	75%
Data Center	$ 2,824,425	80%
Technology (Hardware, Software Licenses, etc.)	$ 1,075,518	25%
Depreciation	$ 2,808,173	39%
External Market Data	$ -	0%
Allocated Shared Expenses	$ 1,156,022	15%
TOTAL	**$14,970,454**	**23.5%**

Below are additional details regarding each of the line-item costs considered by MEMX to be related to offering physical connectivity, as well as any relevant discussion of how the costs projected for 2024 differ, if any, from the Exchange's previous Cost Analysis conducted in 2021 in adopting Connectivity Fees for its Equities platform, which are the same fees the

Exchange is proposing to apply for its Options platform in this filing.[15]

Human Resources

In allocating personnel (Human Resources) costs, in order to not double count any allocations, the Exchange first excluded any employee time allocated towards options regulation in order to recoup costs via the Options Regulatory Fee (''ORF'').[16] Of the remaining employee time left over, MEMX then calculated an allocation of employee time for employees whose functions include providing and maintaining physical connectivity and performance thereof (primarily the MEMX network infrastructure team, which spends most of their time performing functions necessary to provide physical connectivity) and for which the Exchange allocated 80% of each employee's time. The Exchange also allocated Human Resources costs to provide physical connectivity to a limited subset of personnel with ancillary functions related to establishing and maintaining such connectivity (such as information security and finance personnel), for which the Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who do support functions related to providing physical connectivity) and then applied a smaller allocation to such employees (30%).[17] The Exchange notes that it has fewer than 100 employees and each department leader has direct knowledge of the time spent by those spent by each employee with respect to the various tasks necessary to operate the Exchange. The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing physical connectivity, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of their time such employees devote to tasks related to providing physical connectivity. The Exchange notes that senior level executives were only allocated Human Resources costs to the extent the Exchange believed they are involved in overseeing tasks related to providing physical connectivity. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

In 2021, 13.8% of the Exchange's Human Resources costs were allocated towards the provision of physical connectivity, which is slightly lower than the 18% allocation in the current Cost Analysis. The Exchanges notes that this increase is due to additional hiring necessary to support network infrastructure, and that in advance of the launch of MEMX Options, this hiring started at the beginning of 2023.

Connectivity

The Connectivity cost includes external fees paid to connect to other exchanges and third parties. The Exchange notes that its connectivity to external markets is required in order to receive market data to run the Exchange's matching engine and basic operations compliant with existing regulations, primarily Regulation NMS. Approximately 75% of the Exchange's connectivity costs are allocated towards the provision of physical connectivity, which is the same percentage identified in the 2021 Cost Analysis. Of note, the 2021 Cost Analysis allocated approximately $162,000 per month of connectivity costs towards physical connectivity, which is notably higher than the $61,018[18] per month allocated under the current Cost Analysis. The Exchange notes that this is due to a substantial redesign in the Exchange's connectivity plan which achieved the cost savings noted. Additionally, in the 2021 Cost Analysis, certain costs were included in the Connectivity category that have since been moved into the broader Technology category.

Data Center

Data Center costs include an allocation of the costs the Exchange incurs to provide physical connectivity in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange notes that it does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties. The Exchange has allocated a high percentage of the Data Center cost (80%) to physical connectivity because the third-party data centers and the Exchange's physical equipment contained therein is the most direct cost in providing physical access to the Exchange. In other words, for the Exchange to operate in a dedicated space with connectivity of participants to a physical trading platform, the data centers are a very tangible cost, and in turn, if the Exchange did not maintain such a presence then physical connectivity would be of no value to market participants. This slight increase over the allocation of Data Center costs to physical connectivity from 2021 (75%) is due to the Exchange's determination that the Data Center is more directly linked to physical connectivity than any other core service provided by the Exchange.

Technology

The Technology category includes the Exchange's network infrastructure, other hardware, software, and software licenses used to operate and monitor physical assets necessary to offer physical connectivity to the Exchange. Of note, certain of these costs were included in the Connectivity and a separate Hardware and Software Licenses category in the 2021 Cost Analysis; however, in order to align more closely with the Exchange's audited financial statements these costs were combined into the broader Technology category. The Exchange allocated approximately 25% of its Technology costs to physical connectivity in 2024.

Depreciation

All physical assets and software, which also includes assets used for testing and monitoring of Exchange infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes. As noted above, the Exchange allocated 39% of all depreciation costs to providing physical connectivity. This is a higher percentage than was allocated to providing physical connectivity in 2021 (18.5%), and this increase is due to a high amount of capital expenditures required to build the Exchange's options platform, none of which began to depreciate until the launch of options in September 2023. The Exchange notes, however, that it did not allocate depreciation costs for any internally developed software to build the Exchange's trading platforms to physical connectivity, as such software does not impact the provision of physical connectivity.

[15] *See supra* note 5.

[16] *See* Securities Exchange Act Release No. 99259 (January 2, 2024), 89 FR 965 (January 8, 2024) (SR–MEMX–2023–38).

[17] To reiterate, these allocations are applied to the percentage of employee time left over after the ORF allocation. As such, if 10% of an employee's time was allocated towards options regulation, the percentage of time allocated to physical connectivity in this example would apply to the 90% of the employee's time left over.

[18] This figure is arrived at by dividing the annual allocated Connectivity costs in the table on page 12 ($732,216) by 12.

External Market Data

External Market Data includes fees paid to third parties, including other exchanges, to receive and consume market data from other markets. The Exchange notes that it did not allocate any External Market Data fees to the provision of physical connectivity as market data is not related to such services.

Allocated Shared Expenses

Finally, a limited portion of general shared expenses was allocated to physical connectivity as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide physical connectivity. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange notes that the cost of paying directors to serve on its Board of Directors is also included in the Exchange's general shared expenses, and thus a portion of such overall cost amounting to 7% of the overall cost for directors was allocated to providing physical connectivity.

As a final part of the Exchange's analysis related to physical connectivity, the Exchange determined the total *monthly* cost of providing physical connections, (*i.e.* the annual cost of $14,970,454 noted in the table above divided by 12), $1,247,537.83, and projected average monthly revenue for physical connections under the proposed pricing herein of approximately $1,413,500.[19] Thus, the Exchange calculated an average monthly profit of $165,962, resulting in a physical connectivity profit margin of approximately 11.7%.[20] The Exchange notes that this projected profit margin represents an increase over the projected profit margin noted in the 2021 Cost Analysis related to physical connectivity,[21] which is in part due to certain cost savings noted above associated with a redesign in the Exchange's external connectivity plan. Nevertheless, the Exchange believes that the projected profit margin is reasonable and well within the range of where a similarly situated company would expect to be after three years of growth, especially upon launching a new trading platform that provides scale. While the Exchange does not anticipate a significant change to physical connectivity during 2024 (*i.e.,* neither a significant increase nor a significant decrease), it is possible that participants will shift the way that they connect to the Exchange and a reduction occurs or that additional connectivity is established, resulting in an increase.

Costs Related to Offering Application Sessions

The following chart details the individual line-item costs considered by MEMX to be related to offering application sessions as well as the percentage of the Exchange's overall costs such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 11% of its overall Human Resources cost to offering application sessions).

COSTS DRIVER	COSTS	% of ALL
Human Resources	$ 3,664,157	11%
Connectivity	$ 36,020	4%
Data Center	$ 380,202	11%
Technology (Hardware, Software Licenses, etc.)	$ 527,533	12%
Depreciation	$ 1,000,287	14%
External Market Data	$ 367,952	20%
Allocated Shared Expenses	$ 1,209,122	15%
TOTAL	**$7,185,273**	**11.3%**

Human Resources

With respect to application sessions, MEMX calculated Human Resources cost by taking an allocation of employee time for employees whose functions include providing application sessions and maintaining performance thereof (including a broader range of employees such as technical operations personnel, market operations personnel, and software engineering personnel) as well as a limited subset of personnel with ancillary functions related to maintaining such connectivity (such as sales, membership, and finance personnel). The estimates of Human Resources cost were again determined by consulting with department leaders, determining which employees are involved in tasks related to providing application sessions and maintaining performance thereof, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of their time such employees devote to tasks related to providing application sessions and maintaining performance thereof. The Exchange notes that senior level executives were only allocated Human Resources costs to the extent the Exchange believed they are involved in overseeing tasks related to providing application sessions and maintaining performance thereof. The Human Resources cost was again calculated

[19] This projection was based off of actuals earned in January and February 2024 and revenue projections for the remainder of the year based off the number of primary and secondary connections maintained as of February 1, 2024, in both Equities and Options. The Exchange notes that its previous method of estimating profit by dividing the cost of providing physical connectivity by the number of physical connections maintained as of the date of proposed pricing is no longer an accurate method. This is due to the fact that such a calculation assumes that the Exchange earns revenue on all physical connections throughout the entire year, which it will not, given that the Exchange will not begin charging for options connections until March 1, 2024, and that the Exchange earns revenue of $6,000 for all physical connections, regardless of whether such connections are found in the primary or secondary data center, which is also not the case.

[20] The Exchange calculated margin by dividing the total profit ($165,962) by the total revenue ($1,413,500) and multiplying by 100.

[21] The 2021 Cost Analysis projected a profit margin for physical connections of 8%.

using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions. As shown in the table above, for 2024, the Exchange allocated approximately 11% of its Human Resources costs to providing application sessions, which is higher than the 7.7% it allocated in 2021. This increase is again due to additional hiring needed to support the addition of MEMX Options.

Connectivity

The Connectivity cost includes external fees paid to connect to other exchanges, as described above. The Exchange allocated approximately 4% of its Connectivity costs to providing application sessions.

Data Center

Data Center costs include an allocation of the costs the Exchange incurs to provide physical connectivity in the third-party data centers where it maintains its equipment as well as related costs (the Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties). As shown in the table, the Exchange allocated 11% of its Data Center costs to application sessions in the current Cost Analysis, which represents an increase over the 2.6% it allocated in the 2021 Cost Analysis.

Technology

The Technology category includes the Exchange's network infrastructure, other hardware, software, and software licenses used to monitor the health of the order entry services provided by the Exchange. The Exchange allocated 12% of its Technology costs to the provision of application sessions, which represents a slight increase over the 10.1% it allocated in the 2021 Cost Analysis.

External Market Data

External Market Data includes fees paid to third parties, including other exchanges, to receive and consume market data from other markets. The Exchange allocated 20% of External Market Data fees to the provision of application sessions as such market data is necessary to offer certain services related to such sessions, such as validating orders on entry against the National Best Bid and National Best Offer (''NBBO'') and checking for other conditions (*e.g.,* whether a symbol is halted or subject to a short sale circuit breaker). Thus, as market data from other exchanges is consumed at the application session level in order to validate orders before additional processing occurs with respect to such orders, the Exchange believes it is reasonable to allocate a small amount of such costs to application sessions. The increase in allocation of External Market Data costs to the provision of application sessions compared to the 2021 Cost Analysis, in which 7.5% of its External Market Data costs were allocated, is due to a restructuring of the category. Specifically, in 2021, External Market Data only included those costs incurred to receive data from other exchanges, while costs to receive the SIP feeds and other non-exchange data feeds were categorized under Hardware and Software Licenses. These costs are now all categorized under External Market Data.

Depreciation

All physical assets and software, which also includes assets used for testing and monitoring of order entry infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. The Exchange allocated 14% of all depreciation costs to providing application sessions, which represents an increase over the 8.3% allocated in the 2021 Cost Analysis. In contrast to physical connectivity, described above, the Exchange did allocate depreciation costs for depreciated internally developed software to build the Exchange's platforms to application sessions because such software is related to the provision of such connectivity.

Allocated Shared Expenses

Finally, a limited portion of general shared expenses was allocated to overall application session costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide application sessions. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange again notes that the cost of paying directors to serve on its Board of Directors is included in the calculation of Allocated Shared Expenses, and thus a portion of such overall cost amounting to less than 5% of the overall cost for directors was allocated to providing application sessions.

Lastly, the Exchange determined the total *monthly* cost of providing application sessions, (*i.e.* the annual cost of $7,185,273 noted in the table above divided by 12), $598,772.75, and estimated an average monthly revenue from application sessions under the proposed pricing herein of $662,738. Thus, the Exchange calculated an average monthly profit of $63,965, resulting in an application session profit margin of approximately 9.7%.[22] This profit margin for application sessions is slightly higher than the projected profit margin noted in the 2021 Cost Analysis,[23] which the Exchange believes is reasonable and well within the range of where the Exchange would expect it to be at this time.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core services (including physical connectivity or application sessions) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filing it recently submitted proposing the establishment of an ORF.[24] For instance, in calculating the Human Resources expenses to be allocated to physical connections, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a high percentage of the time of such personnel (80%) given their focus on functions necessary to provide physical connections. The time of those same personnel were allocated only 4% to application sessions and the remaining 16% was allocated to transactions and market data. Of note, this allocation applied only to the network infrastructure employee's time that was left over after allocating for options regulation support. The Exchange did not allocate any other Human Resources expense for providing physical connections to any other employee group outside of a smaller allocation

[22] The Exchange calculated margin by dividing the total profit ($63,965) by the total revenue ($662,738) and multiplying by 100.

[23] The 2021 Cost Analysis projected an application session profit margin of approximately 8%.

[24] See *supra* note 16.

(30%) of the employee time associated with certain specified personnel who work closely with and support network infrastructure personnel. In contrast, the Exchange allocated much smaller percentages of employee time (15% or less) across a wider range of personnel groups in order to allocate Human Resources costs to providing application sessions. This is because a much wider range of personnel are involved in functions necessary to offer, monitor and maintain application sessions but the tasks necessary to do so are not a primary or full-time function.

In total, the Exchange allocated 18% of its Human Resources costs to providing physical connections and 11% of its Human Resources costs to providing application sessions, for a total allocation of 29% of its Human Resources expense to provide connectivity services. In turn, the Exchange allocated the remaining 71% of its Human Resources expense to Regulatory Services (21%), membership (2%) and transactions and market data (48%). Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including physical connections and application sessions, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide connectivity services to its Members and non-Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing connectivity services, but instead allocated approximately 53% of the Exchange's overall depreciation and amortization expense to connectivity services (39% attributed to physical connections and 14% to application sessions). The Exchange allocated the remaining depreciation and amortization expense (approximately 47%) toward regulatory services (approximately 6%), and to providing transaction services and market data (approximately 41%).

Looking at the Exchange's operations holistically, the estimated total monthly costs to the Exchange for offering core services in 2024 is $5,299,754, compared to the $3,954,537 noted in the 2021 Cost Analysis. Based on its projections, the Exchange expects to collect approximately $2,076,238 on a monthly basis for connectivity services. Incorporating this amount into the Exchange's overall projected revenue, including projections related to the ORF, the Exchange anticipates monthly revenue of approximately $6,080,631 from all sources (*i.e.,* connectivity fees and membership fees, transaction fees, ORF, and revenue from market data, both through the fees adopted in April 2022 [25] and through the revenue received from the SIPs). As such, applying the Exchange's holistic Cost Analysis to a holistic view of anticipated revenues, the Exchange would earn approximately 13% margin on its operations as a whole. The Exchange believes that this amount is reasonable.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. As a new entrant to the hyper-competitive exchange environment, and an exchange focused on driving competition, the Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from connectivity, the Exchange will have to be successful in retaining existing options clients that wish to maintain physical connectivity and/or application sessions or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis was based on the Exchange's current operations and projections for the remainder of 2024. As such, the Exchange believes that its costs will remain relatively similar in future years (as demonstrated by the comparison of the 2021 Cost Analysis to the 2024 Cost Analysis). It is possible however that such costs will either decrease or increase. To the extent the Exchange sees growth in use of connectivity services it will receive additional revenue to offset future cost increases. However, if use of connectivity services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange would propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Proposed Fees

Physical Connectivity Fees

MEMX offers its Members the ability to connect to the Exchange in order to transmit orders to and receive information from the Exchange. Members can also choose to connect to MEMX indirectly through physical connectivity maintained by a third-party extranet. Extranet physical connections may provide access to one or multiple Members on a single connection. Users of MEMX physical connectivity services (both Members and non-Members [26]) seeking to establish one or more connections with the Exchange submit a request to the Exchange via the MEMX User Portal or directly to Exchange personnel. Upon receipt of the completed instructions, MEMX establishes the physical connections requested by the User. The number of physical connections assigned to each User (for both equities and options) as of October 1, 2023, ranges from one (1)

[25] *See* Securities Exchange Act Release No. 97130 (March 13, 2013), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04).

[26] *See supra* note 3.

to 46, depending on the scope and scale of the Member's trading activity on the Exchange as determined by the Member, including the Member's determination of the need for redundant connectivity. Separate physical connections are not required to access the Exchange's Options and Equities platforms, as such, a User could use a single connection to access both platforms. The Exchange notes that 50% of its Members do not maintain a physical connection directly with the Exchange in the Primary Data Center (though many such Members have connectivity through a third-party provider) and 21 members, or 27.6% have either one or two physical ports to connect to the Exchange in the Primary Data Center.[27] Thus, only a limited number of Members, (17 members, or 22%), maintain three or more physical ports to connect to the Exchange in the Primary Data Center.[28]

As described above, the Exchange has previously justified its pricing with respect to MEMX Equities and believes the most fair approach, absent a significant differentiation between application costs to Equities and Options, is to apply the same pricing to all participants of either platform. As such, in order to cover the aggregate costs of providing physical connectivity to Options and Equities Users and make a modest profit, as described below, the Exchange is proposing to charge a fee of $6,000 per month for each physical connection in the Primary Data Center and a fee of $3,000 per month for each physical connection in the Secondary Data Center for connections to its Options platform, as it currently charges for connections to its Equities platform. There is no requirement that any Member maintain a specific number of physical connections and a Member may choose to maintain as many or as few of such connections as each Member deems appropriate. Further, as noted above, existing Equities Members may choose to use their existing physical connection(s) to access the Exchange's Options platform.

The Exchange notes, however, that pursuant to Rule 2.4 (Mandatory Participation in Testing of Backup Systems), the Exchange does require a small number of Members to connect and participate in functional and performance testing as announced by the Exchange, which occurs at least once every 12 months. Specifically, Members that have been determined by the Exchange to contribute a meaningful percentage of the Exchange's overall volume must participate in mandatory testing of the Exchange's backup systems (*i.e.,* such Members must connect to the Secondary Data Center). The Exchange notes that designated Members are still able to use third-party providers of connectivity to access the Exchange at its Secondary Data Center, and that for its Equities platform, one of eight such designated Members does use a third-party provider instead of connecting directly to the Secondary Data Center through connectivity provided by the Exchange. Nonetheless, because some Members are required to connect to the Secondary Data Center pursuant to Rule 2.4 and to encourage Exchange Members to connect to the Secondary Data Center generally, the Exchange has proposed to charge one-half of the fee for a physical connection in the Primary Data Center for its Options platform, as it currently charges for Equities. The Exchange notes that its costs related to operating the Secondary Data Center were not separately calculated for purposes of this proposal, but instead, all costs related to providing physical connections were considered in the aggregate. The Exchange believes this is appropriate because had the Exchange calculated such costs separately and then determined the fee per physical connection that would be necessary for the Exchange to cover its costs for operating the Secondary Data Center, the costs would likely be much higher than those proposed for connectivity at the Primary Data Center because Members maintain significantly fewer connections at the Secondary Data Center. The Exchange believes that charging a higher fee for physical connections at the Secondary Data Center would be inconsistent with its objective of encouraging Members to connect at such data center and is inconsistent with the fees charged by other exchanges, which also provide connectivity for disaster recovery purposes at a discounted rate.[29]

The proposed fee will not apply differently based upon the size or type of the market participant, but rather based upon the number of physical connections a User requests, based upon factors deemed relevant by each User (either a Member, service bureau or extranet). The Exchange believes these factors include the costs to maintain connectivity, business model and choices Members make in how to participate on the Exchange, as further described below.

The proposed fee of $6,000 per month for physical connections at the Primary Data Center is designed to permit the Exchange to cover the costs allocated to providing connectivity services with a modest profit margin (approximately 11.7%), which would also help fund future expenditures (increased costs, improvements, etc.). The Exchange believes it is appropriate to charge fees that represent a reasonable markup over cost given the other factors discussed above and the need for the Exchange to maintain a highly performant and stable platform to allow Members to transact with determinism.

As noted above, the Exchange proposes a discounted rate of $3,000 per month for physical connections at its Secondary Data Center. The Exchange has proposed this discounted rate for Secondary Data Center connectivity in order to encourage Members to establish and maintain such connections. Also, as noted above, a small number of Members are required pursuant to Rule 2.4 to connect and participate in testing of the Exchange's backup systems, and the Exchange believes it is appropriate to provide a discounted rate for physical connections at the Secondary Data Center given this requirement. The Exchange notes that this rate is well below the cost of providing such services and the Exchange will operate its network and systems at the Secondary Data Center without recouping the full amount of such cost through connectivity services.

The proposed fee for physical connections is effective on filing and will become operative immediately, subject to the proposed waiver described below.

Application Session Fees

Similar to other exchanges, MEMX offers its Members application sessions, also known as logical ports, for order entry and receipt of trade execution reports and order messages. Members can also choose to connect to MEMX indirectly through a session maintained by a third-party service bureau. Service bureau sessions may provide access to one or multiple Members on a single session. Users of MEMX connectivity services (both Members and non-Members [30]) seeking to establish one or more application sessions with the Exchange submit a request to the Exchange via the MEMX User Portal or directly to Exchange personnel. Upon receipt of the completed instructions, MEMX assigns the User the number of

[27] Of those 21 members, four (4) have designated certain of their physical ports will be used to connect to MEMX Options.

[28] Of those 17 members, thirteen (13) have designated certain of their physical ports will be used to connect to MEMX Options.

[29] *See, e.g.,* the BZX options fee schedule, available at *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.*

[30] *See supra* note 3.

sessions requested by the User. The number of sessions assigned to each User as of February 1, 2024, ranges from one (1) to more than 300 depending on the scope and scale of the Member's trading activity on the Exchange (either through a direct connection or through a service bureau) as determined by the Member. For example, by using multiple sessions, Members can segregate order flow from different internal desks, business lines, or customers. The Exchange does not impose any minimum or maximum requirements for how many application sessions a Member or service bureau can maintain, and it is not proposing to impose any minimum or maximum session requirements for its Members or their service bureaus. The same application session cannot be used to access both MEMX Equities and MEMX Options, as such, Users will need to purchase separate application sessions for MEMX Options, which differs from physical connections.

As described above, in order to cover the aggregate costs of providing application sessions to Options Users and to make a modest profit, as described below, the Exchange is proposing to charge a fee of $450 per month for each Order Entry Port and Drop Copy Port in the Primary Data Center for Options application sessions, which is the same fee it currently charges for Equities application sessions. The Exchange notes that it does not propose to charge for: (1) Order Entry Ports or Drop Copy Ports in the Secondary Data Center, or (2) any Test Facility Ports or MEMOIR Gap Fill Ports, again, which it does not charge for Equities Users. The Exchange has proposed to continue to provide Order Entry Ports and Drop Copy Ports in the Secondary Data Center for Options free of charge in order to encourage Members to connect to the Exchange's backup trading systems. Similarly, because the Exchange wishes to encourage Members to conduct appropriate testing of their use of the Exchange, the Exchange has not proposed to charge for Test Facility Ports. With respect to MEMOIR Gap Fill ports, such ports are exclusively used in order to receive information when a market data recipient has temporarily lost its view of MEMX market data. The Exchange has not proposed charging for such ports because the costs of providing and maintaining such ports is more directly related to producing market data.

The proposed fee of $450 per month for each Order Entry Port and Drop Copy Port in the Primary Data Center is designed to permit the Exchange to cover the costs allocated to providing application sessions with a modest profit margin (approximately 9.7%), which would also help fund future expenditures (increased costs, improvements, etc.).

The proposed fee is also designed to encourage Users to be efficient with their application session usage, thereby resulting in a corresponding increase in the efficiency that the Exchange would be able to realize in managing its aggregate costs for providing connectivity services. There is no requirement that any Member maintain a specific number of application sessions and a Member may choose to maintain as many or as few of such ports as each Member deems appropriate. The Exchange has designed its platform such that Order Entry Ports can handle a significant amount of message traffic (*i.e.,* over 50,000 orders per second), and has no application flow control or order throttling. In contrast, other exchanges maintain certain thresholds that limit the amount of message traffic that a single logical port can handle.[31] As such, while several Members maintain a relatively high number of ports because that is consistent with their usage on other exchanges and is preferable for their own reasons, the Exchange believes that it has designed a system capable of allowing such Members to significantly reduce the number of application sessions maintained.

The proposed fee will not apply differently based upon the size or type of the market participant, but rather based upon the number of application sessions a User requests, based upon factors deemed relevant by each User (either a Member or service bureau on behalf of a Member). The Exchange believes these factors include the costs to maintain connectivity and choices Members make in how to segment or allocate their order flow.[32]

The proposed fee for application sessions is effective on filing and will become operative immediately, subject to the proposed waiver described below.

Proposed Fees—Additional Discussion

As discussed above, the proposed fees for connectivity services do not by design apply differently to different types or sizes of Members. As discussed in more detail in the Statutory Basis section, the Exchange believes that the likelihood of higher fees for certain Members subscribing to connectivity services usage than others is not unfairly discriminatory because it is based on objective differences in usage of connectivity services among different Members. The Exchange's incremental aggregate costs for all connectivity services are disproportionately related to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting and support services, resulting in a much higher cost to the Exchange to provide such connectivity services. For these reasons, MEMX believes it is not unfairly discriminatory for the Members with higher message traffic and/or Members with more complicated connections to pay a higher share of the total connectivity services fees. While Members with a business model that results in higher relative inbound message activity or more complicated connections are projected to pay higher fees, the level of such fees is based solely on the number of physical connections and/or application sessions deemed necessary by the Member and not on the Member's business model or type of Member. The Exchange notes that the correlation between message traffic and usage of connectivity services is not completely aligned because Members individually determine how many physical connections and application sessions to request, and Members may make different decisions on the appropriate ways based on facts unique to their individual businesses. Based on the Exchange's architecture, as described above, the Exchange believes that a Member even with high message traffic would be able to conduct business on the Exchange with a

[31] *See, e.g.,* Cboe US Options BOE Specification, *available at: https://cdn.cboe.com/resources/membership/US_Options_BOE_Specification.pdf* (describing a 5,000 message per second Port Order Rate Threshold on Cboe BOE ports).

[32] The Exchange understands that some Members (or service bureaus) may also request more Order Entry Ports to enable the ability to send a greater number of simultaneous order messages to the Exchange by spreading orders over more Order Entry Ports, thereby increasing throughput (*i.e.,* the potential for more orders to be processed in the same amount of time). The degree to which this usage of Order Entry Ports provides any throughput advantage is based on how a particular Member sends order messages to MEMX, however the Exchange notes that its architecture reduces the impact or necessity of such a strategy. All Order Entry Ports on MEMX provide the same throughput, and as noted above, the throughput is likely adequate even for a Member sending a significant amount of volume at a fast pace, and is not artificially throttled or limited in any way by the Exchange.

relatively small connectivity services footprint.

Finally, the fees for connectivity services will help to encourage connectivity services usage in a way that aligns with the Exchange's regulatory obligations. As a national securities exchange, the Exchange is subject to Regulation Systems Compliance and Integrity (''Reg SCI'').[33] Reg SCI Rule 1001(a) requires that the Exchange establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that its Reg SCI systems have levels of capacity adequate to maintain the Exchange's operational capability and promote the maintenance of fair and orderly markets.[34] By encouraging Users to be efficient with their usage of connectivity services, the proposed fee will support the Exchange's Reg SCI obligations in this regard by ensuring that unused application sessions are available to be allocated based on individual User needs and as the Exchange's overall order and trade volumes increase. Additionally, because the Exchange will charge a lower rate for a physical connection to the Secondary Data Center and will not charge any fees for application sessions at the Secondary Data Center or its Test Facility, the proposed fee structure will further support the Exchange's Reg SCI compliance by reducing the potential impact of a disruption should the Exchange be required to switch to its Disaster Recovery Facility and encouraging Members to engage in any necessary system testing with low or no cost imposed by the Exchange.[35]

(ii) Organizational Fee Schedule Changes

The Exchange is proposing to more clearly separate Connectivity Fees from the Exchange's current fee schedule. Currently, the Exchange has separate transaction fee schedules for Equities and Options, and the current Connectivity Fees appear solely on the Equities fee schedule. The Exchange proposes to remove the Connectivity Fees section from the Equities fee schedule, and add hyperlinks at the bottom of the Equities and Options fee schedules that direct the User to a single Connectivity fee schedule. The Exchange believes this format is appropriate given that the same Connectivity Fees apply to both Equities and Options Users, and separating out the fee schedule for Connectivity Fees will reduce potential confusion (*e.g.,* as to which fees a Member that participates on both MEMX Equities and MEMX Options must pay on a monthly basis to maintain connectivity to the Exchange).

The Exchange also proposes to add three additional bullet points to the new Connectivity Fee Schedule related to MEMX Options. The first will notify Members that a physical connection can be used to access MEMX Equities and/or MEMX Options. The second will clarify that an application session can only be used to access one MEMX platform, *i.e.,* MEMX Equities or MEMX Options. The third will note that Connectivity and application session fees solely related to participation on MEMX Options are waived until March 1, 2024.[36] The Exchange notes that the existing bullet points related to Connectivity and application sessions will be included on the proposed separate Connectivity Fee Schedule, (*i.e.,* detailing the Exchange's billing practices, and making clear that that the Exchange does not charge for: (1) Order Entry Ports or Drop Copy Ports in the Secondary Data Center, or (2) any Test Facility Ports or MEMOIR Gap Fill Ports.

2. Statutory Basis

The Exchange believes that the proposed fees for connectivity services to MEMX Options are reasonable, equitable and not unfairly discriminatory because, as described above, the proposed pricing for connectivity services is directly related to the relative costs to the Exchange to provide those respective services and does not impose a barrier to entry to smaller participants.

The Exchange recognizes that there are various business models and varying sizes of market participants conducting business on the Exchange. The Exchange's incremental aggregate costs for all connectivity services are disproportionately related to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting and support services, resulting in a much higher cost to the Exchange to provide such connectivity services. Accordingly, the Exchange believes the allocation of the proposed fees that increase based on the number of physical connections or application sessions is reasonable based on the resources consumed by the respective type of market participant (*i.e.,* lowest resource consuming Members will pay the least, and highest resource consuming Members will pay the most), particularly since higher resource consumption translates directly to higher costs to the Exchange.

With regard to reasonableness, the Exchange understands that when appropriate given the context of a proposal the Commission has taken a market-based approach to examine whether the SRO making the proposal was subject to significant competitive forces in setting the terms of the proposal. In looking at this question, the Commission considers whether the SRO has demonstrated in its filing that: (i) there are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the SRO taking supra-competitive profits. If the SRO demonstrates that the fee is subject to significant competitive forces, the Commission will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. If the filing fails to demonstrate that the fee is constrained by competitive forces, the SRO must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

MEMX believes the proposed fees for connectivity services are fair and reasonable as a form of cost recovery for the Exchange's aggregate costs of offering connectivity services to Members and non-Members. The proposed fees are expected to generate monthly revenue of $2,076,238 providing cost recovery to the Exchange for the aggregate costs of offering

[33] 17 CFR 242.1000–1007.

[34] 17 CFR 242.1001(a).

[35] While some Members might directly connect to the Secondary Data Center and incur the proposed $3,000 per month fee, there are other ways to connect to the Exchange, such as through a service bureau or extranet, and because the Exchange is not imposing fees for application sessions in the Secondary Data Center, a Member connecting through another method would not incur any fees charged directly by the Exchange. However, the Exchange notes that a third-party service provider providing connectivity to the Exchange likely would charge a fee for providing such connectivity; such fees are not set by or shared in by the Exchange.

[36] On February 8, 2024, the Exchange filed a proposed rule change to amend the Exchange's Fee Schedule to extend the existing Membership Fee and Options Connectivity Fee Waivers until February 29, 2024. *See* SR–MEMX–2024–05, available at: *https://info.memxtrading.com/category/rule-filings/effective-rule-filings/.*

connectivity services, based on a methodology that narrowly limits the cost drivers that are allocated cost to those closely and directly related to the particular service. In addition, this revenue will allow the Exchange to continue to offer, to enhance, and to continually refresh its infrastructure as necessary to offer a state-of-the-art trading platform. The Exchange believes that, consistent with the Act, it is appropriate to charge fees that represent a reasonable markup over cost given the other factors discussed above. The Exchange also believes the proposed fee is a reasonable means of encouraging Users to be efficient in the connectivity services they reserve for use, with the benefits to overall system efficiency to the extent Members and non-Members consolidate their usage of connectivity services or discontinue subscriptions to unused physical connectivity.

The Exchange further believes that the proposed fees, as they pertain to purchasers of each type of connectivity alternative, constitute an equitable allocation of reasonable fees charged to the Exchange's Members and non-Members and are allocated fairly amongst the types of market participants using the facilities of the Exchange.

As described above, the Exchange believes the proposed fees are equitably allocated because the Exchange's incremental aggregate costs for all connectivity services are disproportionately related to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting and support services, resulting in a much higher cost to the Exchange to provide such connectivity services.

Commission staff previously noted that the generation of supra-competitive profits is one of several potential factors in considering whether an exchange's proposed fees are consistent with the Act.[37] As described in the Fee Guidance, the term ''supra-competitive profits'' refers to profits that exceed the profits that can be obtained in a competitive market. The proposed fee structure would not result in excessive pricing or supra-competitive profits for the Exchange. The proposed fee structure is merely designed to permit the Exchange to cover the costs allocated to providing connectivity services with a modest margin (approximately 11.7% for physical connectivity and 9.7% for application sessions), which would also help fund future expenditures (increased costs, improvements, etc.). While the Fee Guidance did not establish a guideline as to what constitutes supra-competitive pricing through analyzing margin (nor does the Exchange believe it should have), the Exchange does not believe that it would be reasonable to consider the aforementioned margins to constitute supra-competitive pricing. As noted above, the increase in margin for connectivity services is primarily driven by certain cost savings that the Exchange has been able to achieve as compared to the 2021 Cost Analysis, and the Exchange does not believe it should be penalized, and instead should be rewarded for identifying and realizing such savings. Of course, should the Exchange find opportunities to dramatically reduce costs or increase revenues such that it believes the cost it is charging for physical connections or applications sessions is inconsistent with the cost of providing such connectivity or resulting in unreasonable margin, the Exchange will seek to lower its fees in order to pass savings on to its constituents. Thus, the Exchange believes that its proposed pricing for Connectivity Fees is fair, reasonable, and equitable. Further, the Exchange notes that certain of its competitors have connectivity fees that were approved without the presentation of a cost-based analysis, but it is reasonable to assume that certain of those competitors with significantly higher fees also operate with significantly higher profit margins. Accordingly, the Exchange believes that its proposal is consistent with Section 6(b)(4)[38] of the Act because the proposed fees will permit recovery of the Exchange's costs and will not result in excessive pricing or supra-competitive profit.

The proposed fees for Options connectivity services will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide the connectivity services. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by adopting fees for connectivity services. As detailed above, the Exchange has four primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue. The Exchange's Cost Analysis estimates the monthly costs to provide connectivity services at $1,846,310.58. Based on current connectivity services usage, the Exchange would generate monthly revenues of approximately $2,076,238. This represents a modest profit when compared to the cost of providing connectivity services and that profit represents a modest increase over the profit estimated in the 2021 Cost Analysis (a reasonable goal for a newly formed business, *i.e.,* growing from non-profitable, to break-even to modestly profitable).[39] Even if the Exchange earns that amount or incrementally more, the Exchange believes the proposed fees for connectivity services are fair and reasonable because they will not result in excessive pricing or supra-competitive profit, when comparing the total expense of MEMX associated with providing connectivity services versus the total projected revenue of the Exchange associated with network connectivity services.

As noted above, when incorporating the projected revenue from connectivity services into the Exchange's overall projected revenue, including projections related to recently adopted market data fees, the Exchange anticipates monthly revenue of $6,080,631 from all sources. As such, applying the Exchange's holistic Cost Analysis to a holistic view of anticipated revenues, the Exchange would earn approximately 13% margin on its operations as a whole. The Exchange believes that this amount is reasonable and is again evidence that the Exchange will not earn a supra-competitive profit.

The Exchange notes that other exchanges offer similar connectivity options to market participants and that the Exchange's fees are a discount as compared to the majority of such fees.[40]

[37] *See* Fee Guidance, *supra* note 12.

[38] 15 U.S.C. 78f(b)(4).

[39] Specifically, in the 2021 Cost Analysis, the Exchange estimated the total costs to provide connectivity services at $1,143,715 and estimated monthly revenues of $1,233,750.

[40] One significant differentiation between the Exchanges is that while it offers different types of

Continued

With respect to physical connections, MIAX Options (''MIAX''), MIAX Pearl, LLC (''MIAX Pearl''), MIAX Emerald, LLC (''MIAX Emerald''), each of the Nasdaq Stock Market LLC (''Nasdaq'') options exchanges,[41] NYSE American Options (''NYSE American''), NYSE Arca Options (''NYSE Arca''), Cboe Exchange, Inc. (''Cboe Options''), Cboe BZX Options (''BZX Options''), and Cboe EDGX Options (''EDGX Options'') charge between $7,000-$22,000 per month for physical connectivity at their primary data centers that is comparable to that offered by the Exchange.[42] Nasdaq, NYSE American and NYSE Arca also charge installation fees, which are not proposed to be charged by the Exchange. With respect to application sessions, BX, PHLX, GEMX, MRX, BOX Options (''BOX''), Cboe Options, BZX Options and EDGX charge between $500-$800 per month for order entry and drop ports.[43] The Exchange further notes that several of these exchanges each charge for other logical ports that the Exchange will continue to provide for free, such as application sessions for testing and disaster recovery purposes.[44] While the Exchange's proposed Options Connectivity Fees are lower than certain of the fees charged by the Nasdaq options exchanges, MIAX Options, MIAX Pearl, MIAX Emerald, NYSE American, NYSE Arca, BOX, Cboe, BZX and EDGX, MEMX believes that it offers significant value to Members over these other exchanges in terms of bandwidth available over such connectivity services, which the Exchange believes is a competitive advantage, and differentiates its connectivity versus connectivity to other exchanges.[45] Additionally, the Exchange's proposed Connectivity Fees to its disaster recovery facility are within the range of the fees charged by other exchanges for similar connectivity alternatives.[46] The Exchange believes that its proposal to offer certain application sessions free of charge is reasonable, equitably allocated and not unfairly discriminatory because such proposal is intended to encourage Member connections and use of backup and testing facilities of the Exchange, and, with respect to MEMOIR Gap Fill ports, such ports are used exclusively in connection with the receipt and processing of market data from the Exchange.

In conclusion, the Exchange submits that its proposed fee structure satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act [47] for the reasons discussed above in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities, does not permit unfair discrimination between customers, issuers, brokers, or dealers, and is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and in general to protect investors and the public interest, particularly as the proposal neither targets nor will it have a disparate impact on any particular category of market participant.

The Exchange believes that the proposed reorganization of its fee schedule to establish a separate fee schedule for Connectivity Fees is reasonable and equitable because it is a non-substantive change and does not involve changing any existing fees or rebates that apply to trading activity on MEMX Equities. Further, the changes are designed to make the fee schedule easier to read and for Members to validate the bills they receive from the Exchange. The Exchange also believes this reorganization is non-discriminatory because it applies uniformly to all Members. The Exchange believes the proposed fee schedule will be clearer and less confusing for Members of the Exchange and will eliminate potential Member confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market, and in general, protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[48] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that the proposed rule change to apply the same Connectivity Fees to Options Users as it does to Equities Users would place certain market participants at the Exchange at a relative disadvantage compared to other market participants because the proposed connectivity pricing is associated with relative usage of the Exchange by each market participant and does not impose a barrier to entry to smaller participants. As noted above, the Exchange has previously justified its pricing with respect to MEMX Equities and believes the most fair approach, absent a significant differentiation between application costs to Equities and Options, is to apply the same pricing to all participants of either platform. The Exchange believes its proposed pricing is reasonable and lower than what other options exchanges charge and, when coupled with the availability of third-party providers that also offer connectivity solutions, that participation on the Exchange is

physical connections, including 10Gb, 25Gb, 40Gb, and 100Gb connections, the Exchange does not propose to charge different prices for such connections. In contrast, most of the Exchange's competitors provide scaled pricing that increases depending on the size of the physical connection. The Exchange does not believe that its costs increase incrementally based on the size of a physical connection but instead, that individual connections and the number of such separate and disparate connections are the primary drivers of cost for the Exchange.

[41] Including Nasdaq PHLX (''PHLX''), Nasdaq Options Market (''NOM''), Nasdaq BX Options (''BX''), Nasdaq ISE (''ISE''), Nasdaq GEMX (''GEMX''), and Nasdaq MRX (''MRX'').

[42] *See* the MIAX fee schedule, available at: *https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX__Options__Fee__Schedule_10022023.pdf;* the MIAX Pearl fee schedule, available at: *https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_09122023.pdf;* the MIAX Emerald fee schedule, available at: *https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Emerald_Fee_Schedule_10122023_3.pdf;* the Nasdaq Options markets fee schedule, at *http://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2;* the NYSE Connectivity fee schedule, at: *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf* ; the Cboe fee schedule, at: *https://www.cboe.com/us/options/membership/fee_schedule/cone/;* the BZX Options fee schedule, available at: *https://www.cboe.com/us/options/membership/fee_schedule/bzx/;* the EDGX Options fee schedule, available at: *https://www.cboe.com/us/options/membership/fee_schedule/edgx/,* and the BOX Options fee schedule, available at: *https://boxoptions.com/fee-schedule/.* This range is based on a review of the fees charged for 10–40Gb connections at each of these exchanges and relates solely to the physical port fee or connection charge, excluding co-location fees and other fees assessed by these exchanges. The Exchange notes that it does not offer physical connections with lower bandwidth than 10Gb and that Members and non-Members with lower bandwidth requirements typically access the Exchange through third-party extranets or service bureaus.

[43] *See id.*

[44] *See id.*

[45] As noted above, all physical connections offered by MEMX are at least 10Gb capable and physical connections provided with larger bandwidth capabilities will be provided at the same rate as such connections. In contrast to other exchanges, MEMX has not proposed different types of physical connections with higher pricing for those with greater capacity. *See supra* note 39. The Exchange also reiterates that MEMX application sessions are capable of handling significant amount of message traffic (*i.e.,* over 50,000 orders per second), and have no application flow control or order throttling, in contrast to competitors that have imposed message rate thresholds. *See supra* note 32 and accompanying text.

[46] *See supra* note 42.

[47] 15 U.S.C. 78f(b)(4) and (5).

[48] 15 U.S.C. 78f(b)(8).

affordable for all market participants, including smaller trading firms. Therefore, the fees may stimulate intramarket competition by attracting additional firms to become Members of MEMX Options. As described above, the connectivity services purchased by market participants typically increase based on their additional message traffic and/or the complexity of their operations. The market participants that utilize more connectivity services typically utilize the most bandwidth, and those are the participants that consume the most resources from the network. Accordingly, the proposed fees for connectivity services do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed Connectivity Fees reflects the network resources consumed by the various size of market participants and the costs to the Exchange of providing such connectivity services.

As it relates to the reorganization of the fee schedule, as discussed above, the Exchange does not believe that the proposed change would impose any burden on competition because such change serves to create an easier to read fee schedule to avoid any Member confusion.

Intermarket Competition

The Exchange does not believe the proposed fees for Options Connectivity place an undue burden on competition on other SROs that is not necessary or appropriate. Additionally, other exchanges have similar connectivity alternatives for their participants, but with higher rates to connect.[49] The Exchange is also unaware of any assertion that the proposed fees for connectivity services would somehow unduly impair its competition with other exchanges. As a new entrant in an already highly competitive environment for equity options trading, MEMX does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Exchange Act. In sum, MEMX's proposed Connectivity Fees for Options Members are comparable to and generally lower than fees charged by other options exchanges for the same or similar services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[50] and Rule 19b–4(f)(2)[51] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MEMX–2024–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MEMX–2024–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MEMX–2024–06 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[52]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04695 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

[49] *See supra* notes 41–46 and accompanying text.

[50] 15 U.S.C. 78s(b)(3)(A)(ii).

[51] 17 CFR 240.19b–4(f)(2).

[52] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–151, OMB Control No. 3235–0291

Proposed Collection; Comment Request; Extension: Rules 17Ad–6 and 17Ad–7

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ad–6 (17 CFR 240.17Ad–6) and Rule 17Ad–7 (17 CFR 240.17Ad–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–6 requires every registered transfer agent to make and keep current

records about a variety of information, such as: (1) specific operational data regarding the time taken to perform transfer agent activities (to ensure compliance with the minimum performance standards in Rule 17Ad–2 (17 CFR 240.17Ad–2)); (2) written inquiries and requests by shareholders and broker-dealers and response time thereto; (3) resolutions, contracts, or other supporting documents concerning the appointment or termination of the transfer agent; (4) stop orders or notices of adverse claims to the securities; and (5) all canceled registered securities certificates.

Rule 17Ad–7 requires each registered transfer agent to retain the records specified in Rule 17Ad–6 in an easily accessible place for a period of six months to six years, depending on the type of record or document. Rule 17Ad–7 also specifies the manner in which records may be maintained using electronic, microfilm, and microfiche storage methods.

These recordkeeping requirements are designed to ensure that all registered transfer agents are maintaining the records necessary for them to monitor and keep control over their own performance and for the Commission to adequately examine registered transfer agents on an historical basis for compliance with applicable rules.

The Commission estimates that approximately 315 registered transfer agents will spend a total of 157,500 hours per year complying with Rules 17Ad–6 and 17Ad–7 (500 hours per year per transfer agent).

The retention period under Rule 17Ad–7 for the recordkeeping requirements under Rule 17Ad–6 is six months to six years, depending on the particular record or document. The recordkeeping and retention requirements under Rules 17Ad–6 and 17Ad–7 are mandatory to assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rules. These rules do not involve the collection of confidential information.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by May 6, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: February 29, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04652 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99639; File No. SR–NYSEAMER–2024–12]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Rule 7.19E

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 16, 2024, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.19E to make additional pre-trade risk controls available to Entering Firms and Clearing Firms. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.19E to make additional pre-trade risk controls available to Entering Firms and Clearing Firms.

Background and Proposal

In 2020, in order to assist ETP Holders' efforts to manage their risk, the Exchange amended its rules to add Rule 7.19E (Pre-Trade Risk Controls),[3] which established a set of optional pre-trade risk controls by which Entering Firms and their designated Clearing Firms [4] could set credit limits and other pre-trade risk controls for an Entering Firm's trading on the Exchange and authorize the Exchange to take action if those credit limits or other pre-trade risk controls are exceeded. These pre-trade risk controls include a Gross Credit Risk Limit, which is defined in Rule 7.19E(b)(1) as ''a pre-established maximum daily dollar amount for purchases and sales across all symbols, where both buy and sell orders are counted as positive values.'' The current version of Rule 7.19E(b)(1) specifies that both open and executed orders are considered: ''[f]or purposes of calculating the Gross Credit Risk Limit, unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37E(a)(1), and executed orders are included.''

The Exchange has recently received several requests from market participants to create two additional

[3] *See* Securities Exchange Act Release No. 88878 (May 14, 2020), 85 FR 30770 (May 20, 2020) (SR–NYSEAMER–2020–38). Later, in 2023, the Exchange amended its rules to make additional pre-trade risk controls available to Entering Firms. *See* Securities Exchange Act Release No. 96922 (February 14, 2023), 88 FR 10580 (February 21, 2023) (SR–NYSEAMER–2023–12).

[4] The terms ''Entering Firm'' and ''Clearing Firm'' are defined in Rule 7.19E.

Gross Credit Risk Limit risk controls: one that includes only open orders and another that includes only executed orders. Market participants have explained that Entering Firms and Clearing Firms would benefit from having more granular gross credit risk controls available, which would allow them to set limits and breach actions based solely on open orders or executed orders, in addition to the Exchange's existing Gross Credit Risk Limit that includes both open and executed orders.

The Exchange notes that the MIAX Pearl equities exchange (''MIAX Pearl'') currently offers risk controls substantially similar to those proposed here. Specifically, MIAX Pearl offers its ''Equity Members'' and their ''Clearing Members'' the option to use a ''Gross Notional Trade Value'' risk check, which includes only executed orders, and a ''Gross Notional Open Value'' risk check, which includes only unexecuted orders, in addition to a ''Gross Notional Open and Trade Value'' risk check, for which both executed and unexecuted orders are included.[5] As such, market participants are already familiar with these various gross credit risk checks, such that the ones proposed by the Exchange in this filing are not novel.

In light of these requests, the Exchange proposes to amend Rule 7.19E(b)(1) to rename the existing Gross Credit Risk Limit as ''Gross Credit Risk Limit—Open + Executed,'' and to add two additional risk limits: ''Gross Credit Risk Limit—Open Only'' and ''Gross Credit Risk Limit—Executed Only.''

Specifically, the Exchange proposes to amend and reorganize Rule 7.19E(b)(1) as follows. First, the Exchange would amend the language in the first sentence of the rule to refer to plural Gross Credit Risk Limits, instead of just one. At the end of the first sentence, the Exchange would add that ''[a]vailable Gross Credit Risk Limits include'' the three types described in new sub-sections (A), (B), and (C).

Proposed sub-section (A) would define the ''Gross Credit Risk Limit—Open + Executed'' risk check to include unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37E(a)(1), and executed orders (just as the current Gross Credit Risk Limit does).

Proposed sub-section (B) would define the ''Gross Credit Risk Limit—Open Only'' risk check to include only unexecuted orders in the Exchange Book and orders routed on arrival pursuant to Rule 7.37E(a)(1).

Proposed sub-section (C) would define the ''Gross Credit Risk Limit—Executed Only'' risk check to include executed orders only.

In addition, the Exchange proposes to make a conforming change to section (c)(1)(B) of the rule, to make plural the current singular reference to ''Gross Credit Risk Limit.''

As with the Exchange's existing risk controls, use of the pre-trade risk controls proposed herein would be optional. The Exchange proposes no other changes to Rule 7.19E or its Commentary.

Continuing Obligations of ETP Holders Under Rule 15c3–5

The proposed Pre-Trade Risk Controls described here are meant to supplement, and not replace, the ETP Holders' own internal systems, monitoring, and procedures related to risk management. The Exchange does not guarantee that these controls will be sufficiently comprehensive to meet all of an ETP Holder's needs, the controls are not designed to be the sole means of risk management, and using these controls will not necessarily meet an ETP Holder's obligations required by Exchange or federal rules (including, without limitation, the Rule 15c3–5 under the Act[6] (''Rule 15c3–5'')). Use of the Exchange's Pre-Trade Risk Controls will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the ETP Holder.[7]

Timing and Implementation

The Exchange anticipates implementing the proposed change in the first quarter of 2024 and, in any event, will implement the proposed rule change no later than the end of June 2024. The Exchange will announce the timing of such changes by Trader Update.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed additional Pre-Trade Risk Controls would provide Entering Firms and Clearing Firms with enhanced abilities to manage their risk with respect to orders on the Exchange. The proposed additional Pre-Trade Risk Controls are not novel; they are based on existing risk settings already in place on MIAX Pearl and market participants are already familiar with the types of protections that the proposed risk controls afford.[10] As such, the Exchange believes that the proposed additional Pre-Trade Risk Controls would provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

In addition, the Exchange believes that the proposed rule change will protect investors and the public interest because the proposed additional Pre-Trade Risk Controls are a form of impact mitigation that will aid Entering Firms and Clearing Firms in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that ETP Holders implement a number of different risk-based controls, including those required by Rule 15c3–5. The controls proposed here will serve as an additional tool for Entering Firms and Clearing Firms to assist them in identifying any risk exposure. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's ETP Holders because use of the proposed additional Pre-Trade Risk Controls is optional and is not a prerequisite for participation on the Exchange.

[5] *See* MIAX Pearl Rule 2618(a)(2)(A), (C), and (E).

[6] *See* 17 CFR 240.15c3–5.

[7] *See also* Commentary .01 to Rule 7.19E, which provides that ''[t]he pre-trade risk controls described in this Rule are meant to supplement, and not replace, the ETP Holder's own internal systems, monitoring and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Exchange Act. Responsibility for compliance with all Exchange and SEC rules remains with the ETP Holder.''

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See supra* note 6.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing Entering Firms and Clearing Firms additional means to monitor and control risk, the proposed rule will increase confidence in the proper functioning of the markets. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2024–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEAMER–2024–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–NYSEAMER–2024–12, and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04696 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99646; File No. SR–GEMX–2024–04]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2024, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2017,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[9] in general, and furthers the objectives of section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above,

[3] *See* Securities Exchange Act Release No. 34–62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR–NASDAQ–2010–019). In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Cabinet Proximity Option program. *See* Securities Exchange Act Release No. 34–81902 (October 19, 2017), 82 FR 49453 (October 25, 2017) (SR–GEMX–2017–48).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW.

[6] *See* Securities Exchange Act Release No. 34–81902 (October 19, 2017), 82 FR 49453 (October 25, 2017) (SR–GEMX–2017–48).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange

Continued

the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–GEMX–2024–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–GEMX–2024–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–GEMX–2024–04 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04703 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

is currently working to expand the amount of power and number of cabinets available in colocation.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99645; File No. SR–MRX–2024–03]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2024, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2017,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR–NASDAQ–2010–019). In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Cabinet Proximity Option program. *See* Securities Exchange Act Release No. 34–81907 (October 19, 2017), 82 FR 49447 (October 25, 2017) (SR–MRX–2017–21).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW. s

[6] *See* Securities Exchange Act Release No. 34–81907 (October 19, 2017), 82 FR 49447 (October 25, 2017) (SR–MRX–2017–21).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above, the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MRX–2024–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MRX–2024–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange is currently working to expand the amount of power and number of cabinets available in colocation.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MRX–2024–03 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04702 Filed 3–5–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99644; File No. SR–PHLX–2024–06]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2024, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2010,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–62395 (June 28, 2010), 75 FR 38584 (July 2, 2010) (SR–Phlx–2010–18).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW.

[6] *See* Securities Exchange Act Release No. 34–62395 (June 28, 2010), 75 FR 38584 (July 2, 2010) (SR–Phlx–2010–18).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[9] in general, and furthers the objectives of section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above, the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act[13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange is currently working to expand the amount of power and number of cabinets available in colocation.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PHLX–2024–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PHLX–2024–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PHLX–2024–06 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04701 Filed 3–5–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99642; File No. SR–NYSENAT–2024–04]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31(a)(2)(B)

February 29, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 16, 2024, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31(a)(2)(B) regarding Limit Order Price Protection. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31(a)(2)(B) (''Limit Order Price Protection'') to provide for the application of Limit Order Price Protection during the Core Trading Session even where a contra-side NBB (NBO) has not been established.

Currently, Rule 7.31(a)(2)(B) provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage away from the National Best Offer (National Best Bid) (''NBO'' and ''NBB,'' respectively),[3] and that Limit Order Price Protection will not be applied to an incoming Limit Order to buy (sell) if there is no NBO (NBB).

The Exchange has recently received requests from market participants to modify this rule so that during the Core Trading Session, Limit Order Price Protection would apply even when no contra-side NBB or NBO has been established. In such cases, market participants have suggested that the Limit Order Price Protection calculation should use an alternate reference price, such as the last consolidated round-lot price of the trading day or the prior trading day's official closing price. That way, even if no contra-side NBB or NBO has been established, the Exchange would still apply Limit Order Price Protection using the best-available alternate reference price, thereby offering market participants greater protections against the execution of Limit Orders with aberrant prices during the Core Trading Session. The Exchange is aware that the Limit Order Price Protection rule on the MIAX Pearl equities exchange (''MIAX Pearl'') currently features such a hierarchy of reference prices, so that Limit Order Price Protection is applied to all Limit

[18] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For securities with a reference price between $0.00 and $25.00, the specified percentage is 10%; for securities with a reference price between $25.01 and $50.00, the specified percentage is 5%; and for securities with a reference price greater than $50.00, the specified percentage is 3%.

Orders, even where no contra-side NBB or NBO has been established.[4]

In light of these requests from market participants, the Exchange now proposes to amend Rule 7.31(a)(2)(B) to provide a hierarchy of reference prices against which Limit Order Price Protection would apply during the Core Trading Session. As in the current rule, during the Core Trading Session, a Limit Order to buy (sell) would be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage (as set forth in the accompanying table) away from the NBO (NBB). But if such NBO (NBB) has not yet been established, the Exchange would use as the reference price the last consolidated round-lot price of that trading day, or, if none, the prior trading day's Official Closing Price.[5] This proposal is substantively identical to an immediately-effective rule change recently filed by the Exchange's affiliate exchange, NYSE American LLC (''NYSE American'').[6]

As in the NYSE American filing, the Exchange does not propose for this change to apply during the Early and Late Trading Sessions. This is because with respect to both the Early and Late Trading Sessions, there is a higher likelihood that overnight news developments may move the market more than the percentages specified in the Limit Order Price Protection rule. If, in the absence of an NBO (NBB), such percentages were applied to the prior trading day's Official Closing Price, this might lead the Exchange to reject orders that are appropriately trying to establish a quote at the new market level. For this reason, the Exchange believes the current rule should continue to govern during the Early and Late Trading Sessions, such that if there is no contra-side NBO (NBB), Limit Order Price Protection will not be applied.

Accordingly, the Exchange proposes to amend and reorganize Rule 7.31(a)(2)(B) into three sub-sections, with sub-section (i) describing the relevant reference prices during the Core Trading Session, sub-section (ii) describing the relevant reference price during the Early and Late Trading Sessions, and sub-section (iii) describing the balance of the current rule.

Specifically, the Exchange proposes that new sub-section (i) of Rule 7.31(a)(2)(B) would provide that during the Core Trading Session, a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage (as set forth in the accompanying table) away from ''(a) the NBO (NBB), or, if none, (b) the last consolidated round-lot price of that trading day, or, if none, (c) the prior trading day's Official Closing Price.''

The Exchange proposes that new sub-section (ii) of the rule would provide that during the Early and Late Trading Sessions, a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage (as set forth in the accompanying table) away from the NBO (NBB), and that Limit Order Price Protection will not be applied to an incoming Limit Order to buy (sell) if there is no NBO (NBB).

Finally, the Exchange proposes that the balance of the current rule be moved to new sub-section (iii) after the new subtitle ''Applicability.''

The Exchange does not propose to make any other changes to the rule, nor does it propose any changes to the $0.15 or specified percentages used in the calculation of Limit Order Price Protection.

Implementation

The Exchange anticipates implementing the proposed change in the first quarter of 2024 and, in any event, will implement the proposed rule change no later than the end of June 2024. The Exchange will announce the timing of such changes by Trader Update.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[7] in general, and with section 6(b)(5),[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, protect investors and the public interest, because the use a substantially similar hierarchy of reference prices for the application of Limit Order Price Protection when no contra-side NBO or NBB has been established is currently in effect on MIAX Pearl and is the subject of an immediately-effective rule filing on NYSE American, and therefore is not novel.[9] The Exchange further believes that the proposed change would enhance the Exchange's Limit Order Price Protection mechanism during the Core Trading Session, because it would apply using the best-available alternate reference price when a contra-side NBO or NBB has not been established, thereby offering market participants greater protection from aberrant prices and improving continuous trading and price discovery. In addition, the proposal to enhance Limit Order Price Protection by adding alternative reference prices to apply to the Core Trading Session would assist with the maintenance of fair and orderly markets because such mechanisms protect investors from potentially receiving executions away from the prevailing market prices.

The Exchange also believes that it would protect investors and the public interest for the Exchange to maintain the current Limit Order Price Protection rule for the Early and Late Trading Sessions. With respect to both the Early and Late Trading Sessions, there is a higher likelihood that overnight news developments may move the market more than the percentages specified in the Limit Order Price Protection rule. If, in the absence of an NBO (NBB), such percentages were applied to the prior trading day's Official Closing Price, this might lead the Exchange to reject orders that are appropriately trying to establish a quote at the new market level. For this reason, the Exchange believes that, for the protection of investors and the public interest, the current rule should continue to govern during the Early and Late Trading Sessions, such that if there is no contra-side NBO (NBB), Limit

[4] Under current MIAX Pearl rules, a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of a specified dollar and percentage away from (1) the PBO (PBB), or, if unavailable, (2) the consolidated last sale price disseminated during the Regular Trading Hours on trade date, or, if unavailable, (3) the prior day's Official Closing Price. *See* MIAX Pearl Rule 2614(a)(1)(ix)(A).

[5] The Exchange's proposed hierarchy of reference prices is substantially similar to the hierarchy in the MIAX Pearl rules. The only differences are that the Exchange's proposal (a) would continue to reference the NBO (NBB) instead of the PBO (PBB), as the Exchange's Limit Order Price Protection mechanism has always done; and (b) unlike the MIAX Pearl rule, which permits an odd lot to serve as ''the consolidated last sale price disseminated during the Regular Trading Hours on trade date,'' the Exchange's proposal would instead use the last consolidated round-lot price of that trading day, which the Exchange believes is a better indication of actual market conditions. Both the MIAX Pearl rule and the Exchange's proposed rule would use the prior trading day's Official Closing Price as the reference price of last resort.

[6] *See* Securities Exchange Act Release No.____ (SR–NYSEAMER–2024–11). [sic]

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See supra* notes 5 and 6.

Order Price Protection will not be applied.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change would not address competitive issues but rather would enhance the Exchange's Limit Order Price Protection mechanism, to further protect market participants from aberrant prices and improve continuous trading and price discovery.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B) [12] of the Act to determine whether the proposed rule change should be approved or disapproved.

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(2)(B).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2024–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2024–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENAT–2024–04, and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04699 Filed 3–5–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99633; File No. SR–NASDAQ–2024–007]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand Its Cabinet Proximity Option Program

February 29, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 16, 2024, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Exchange's Cabinet Proximity Option program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers a Cabinet Proximity Option program where, for a monthly fee, customers can obtain an option for future use on available, unused cabinet space in proximity to their existing equipment. Cabinets reserved under the Cabinet Proximity Option program are unused cabinets that customers reserve for future use and can be converted to a powered cabinet at the customer's request. Under the program, customers can reserve up to maximum of 20 cabinets that the Exchange endeavors to provide as close as reasonably possible to the customer's existing cabinet space, taking into consideration power availability within segments of the datacenter and the overall efficiency of use of datacenter resources as determined by the Exchange. Should reserved datacenter space be needed for use, the reserving customer will have three business days to formally contract with the Exchange for full payment for the reserved cabinet space in contention or it will be reassigned. In making determinations to require exercise or relinquishment of reserved space as among numerous customers, the Exchange will take into consideration several factors, including: proximity between available reserved cabinet space and the existing space of a customer seeking additional space for actual cabinet usage; a customer's ratio of cabinets in use to those reserved; the length of time that a particular reservation(s) has been in place; and any other factor that the Exchange deems relevant to ensure overall efficiency in use of the datacenter space.[3]

Currently, the Exchange offers reservations for low, medium, medium/high, or high density cabinets under the Cabinet Proximity Option program.[4] The purpose of the proposed rule change is to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW, in addition to those reservations currently offered under the program.[5] Although the Exchange has offered the Cabinet Proximity Option program since 2010,[6] the Exchange has yet to offer reservations under the Cabinet Proximity Option program for cabinets with power densities greater than 10 kW (despite offering cabinets with power densities greater than 10 kW). The Exchange now wishes to offer the Cabinet Proximity Option program for these higher power density cabinets. Similar to the Exchange's Cabinet Proximity Option program, the New York Stock Exchange LLC (''NYSE'') offers ''PNU cabinets,'' which are reserved cabinets that are not active and can be converted to powered, dedicated cabinets when the user requests.[7] NYSE's PNU cabinets are not limited to certain density cabinets and NYSE charges a fee per kW for PNU cabinets.[8]

The Exchange offers the Cabinet Proximity Option program as a convenience to customers. No firms are required to reserve cabinets via the Cabinet Proximity Option program and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

Implementation

The Exchange intends to submit a fee filing in the future to establish related fees in the existing Cabinet Proximity Option Fees, in General 8, Section 1(d). Implementation of the proposal described herein to offer the Exchange's Cabinet Proximity Option program for cabinets with power densities greater than 10 kW would coincide with the subsequent fee filing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[9] in general, and furthers the objectives of section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal would provide customers with the ability to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for those cabinets with power densities greater than 10 kW. Customers are currently able to obtain an option for future use on available, unused cabinet space in proximity to their existing equipment for smaller cabinets (*e.g.,* for cabinets with power densities less than 10 kW). The proposal is consistent with the Act because it would clarify, in conjunction with a subsequent fee filing, that reservations under the Cabinet Proximity program are available for cabinets with power densities greater than 10 kW. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, which may be offered for cabinets of all power densities (when the unallocated cabinet inventory is more than 40 cabinets).[11] Furthermore, the proposal would benefit the public interest by providing customers more reservation options to choose from, thereby enhancing their ability to tailor their colocation operations to the requirements of their business operations.[12] As noted above, the Exchange offers the Cabinet Proximity Option program as a convenience, not a necessity, and it is only for those customers that choose to collocate directly with the Exchange. Participants can avoid reserving cabinets under this program (and the related fee) by (1) collocating but not reserving space in advance of needing it; (2) ordering cabinet space immediately and paying cabinet fees (without reserving in advance); (3) collocating indirectly through a vendor to defray costs; or (4) not collocating at all.

[3] *See* Securities Exchange Act Release No. 34–62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR–NASDAQ–2010–019).

[4] *See* General 8, Section 1(d). Low density cabinets are cabinets with power densities less than or equal to 2.88 kilowatts (''kW''). Medium density cabinets are cabinets with power densities greater than 2.88 kW and less than or equal to 5 kW. Medium/High density cabinets are cabinets with power densities greater than 5 kW and less than or equal to 7 kW. High density cabinets are cabinets with power densities greater than 7 kW and less than 10 kW. *See* General 8, Section 1(a).

[5] Currently, the Exchange offers Super High Density Cabinets with power densities greater than 10 kW and less than or equal to 17.3 kW. *See* General 8, Section 1(a). In addition, the Exchange intends to offer cabinets with new power densities in the future, including power densities greater than 17.3 kW.

[6] *See* Securities Exchange Act Release No. 34–62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR–NASDAQ–2010–019).

[7] Due to heightened demand for power and cabinets, NYSE established certain procedures related to PNU cabinet conversion and restrictions on new PNU cabinet offerings. NYSE adopted a policy that, if unallocated cabinet inventory is at or below 40 cabinets, new PNU cabinets are not offered. However, when the unallocated cabinet inventory is more than 40 cabinets, NYSE may continue to offer PNU cabinets. *See* Securities Exchange Act Release No. 34–90732 (December 18, 2020), 85 FR 84443 (December 28, 2020). *See also* Securities Exchange Act Release No. 34–91515 (April 8, 2021), 86 FR 19674 (April 14, 2021).

[8] *See* NYSE Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 7.

[12] The Exchange believes that customer demand for power and cabinets will continue. The Exchange is currently working to expand the amount of power and number of cabinets available in colocation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges and other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Cabinet Proximity Option program is comparable to PNU cabinets offered by NYSE, as discussed above.

Nothing in the Proposal burdens intra-market competition because the Cabinet Proximity Option program is available to any customer and customers that wish to make reservations pursuant to the Cabinet Proximity Option program can do so on a non-discriminatory basis. Use of any colocation service is completely voluntary, and each market participant is able to determine whether to use colocation services based on the requirements of its business operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act [13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that a waiver of the operative delay would permit the Exchange to offer reservations under the Cabinet Proximity Option program for cabinets with greater power densities (*e.g.,* greater than 10kW) without delay once a fee is established for such cabinets. The Commission believes that the proposed rule change presents no novel legal or regulatory issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2024–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2024–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2024–007 and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04693 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99634; File No. SR–NYSENAT–2024–03]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.19

February 29, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 16, 2024, NYSE National, Inc. (''NYSE

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

National'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.19 to make additional pre-trade risk controls available to Entering Firms and Clearing Firms. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.19 to make additional pre-trade risk controls available to Entering Firms and Clearing Firms.

Background and Proposal

In 2020, in order to assist ETP Holders' efforts to manage their risk, the Exchange amended its rules to add Rule 7.19 (Pre-Trade Risk Controls),[3] which established a set of optional pre-trade risk controls by which Entering Firms and their designated Clearing Firms [4] could set credit limits and other pre-trade risk controls for an Entering Firm's trading on the Exchange and authorize the Exchange to take action if those credit limits or other pre-trade risk controls are exceeded. These pre-trade risk controls include a Gross Credit Risk Limit, which is defined in Rule 7.19(b)(1) as ''a pre-established maximum daily dollar amount for purchases and sales across all symbols, where both buy and sell orders are counted as positive values.'' The current version of Rule 7.19(b)(1) specifies that both open and executed orders are considered: ''[f]or purposes of calculating the Gross Credit Risk Limit, unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included.''

The Exchange has recently received several requests from market participants to create two additional Gross Credit Risk Limit risk controls: one that includes only open orders and another that includes only executed orders. Market participants have explained that Entering Firms and Clearing Firms would benefit from having more granular gross credit risk controls available, which would allow them to set limits and breach actions based solely on open orders or executed orders, in addition to the Exchange's existing Gross Credit Risk Limit that includes both open and executed orders.

The Exchange notes that the MIAX Pearl equities exchange (''MIAX Pearl'') currently offers risk controls substantially similar to those proposed here. Specifically, MIAX Pearl offers its ''Equity Members'' and their ''Clearing Members'' the option to use a ''Gross Notional Trade Value'' risk check, which includes only executed orders, and a ''Gross Notional Open Value'' risk check, which includes only unexecuted orders, in addition to a ''Gross Notional Open and Trade Value'' risk check, for which both executed and unexecuted orders are included.[5] As such, market participants are already familiar with these various gross credit risk checks, such that the ones proposed by the Exchange in this filing are not novel.

In light of these requests, the Exchange proposes to amend Rule 7.19(b)(1) to rename the existing Gross Credit Risk Limit as ''Gross Credit Risk Limit—Open + Executed,'' and to add two additional risk limits: ''Gross Credit Risk Limit—Open Only'' and ''Gross Credit Risk Limit—Executed Only.''

Specifically, the Exchange proposes to amend and reorganize Rule 7.19(b)(1) as follows. First, the Exchange would amend the language in the first sentence of the rule to refer to plural Gross Credit Risk Limits, instead of just one. At the end of the first sentence, the Exchange would add that ''[a]vailable Gross Credit Risk Limits include'' the three types described in new sub-sections (A), (B), and (C).

Proposed sub-section (A) would define the ''Gross Credit Risk Limit—Open + Executed'' risk check to include unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders (just as the current Gross Credit Risk Limit does).

Proposed sub-section (B) would define the ''Gross Credit Risk Limit—Open Only'' risk check to include only unexecuted orders in the Exchange Book and orders routed on arrival pursuant to Rule 7.37(a)(1).

Proposed sub-section (C) would define the ''Gross Credit Risk Limit—Executed Only'' risk check to include executed orders only.

In addition, the Exchange proposes to make a conforming change to section (c)(1)(B) of the rule, to make plural the current singular reference to ''Gross Credit Risk Limit.''

As with the Exchange's existing risk controls, use of the pre-trade risk controls proposed herein would be optional. The Exchange proposes no other changes to Rule 7.19 or its Commentary.

Continuing Obligations of ETP Holders Under Rule 15c3–5

The proposed Pre-Trade Risk Controls described here are meant to supplement, and not replace, the ETP Holders' own internal systems, monitoring, and procedures related to risk management. The Exchange does not guarantee that these controls will be sufficiently comprehensive to meet all of an ETP Holder's needs, the controls are not designed to be the sole means of risk management, and using these controls will not necessarily meet an ETP Holder's obligations required by Exchange or federal rules (including, without limitation, the Rule 15c3–5 under the Act [6] (''Rule 15c3–5'')). Use of the Exchange's Pre-Trade Risk Controls will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the ETP Holder.[7]

[3] *See* Securities Exchange Act Release No. 88905 (May 19, 2020), 85 FR 31582 (May 26, 2020) (SR–NYSENAT–2020–17). Later, in 2023, the Exchange amended its rules to make additional pre-trade risk controls available to Entering Firms. *See* Securities Exchange Act Release No. 96919 (February 14, 2023), 88 FR 10569 (February 21, 2023) (SR–NYSENAT–2023–07).

[4] The terms ''Entering Firm'' and ''Clearing Firm'' are defined in Rule 7.19.

[5] *See* MIAX Pearl Rule 2618(a)(2)(A), (C), and (E).

[6] *See* 17 CFR 240.15c3–5.

[7] *See also* Commentary .01 to Rule 7.19, which provides that ''[t]he pre-trade risk controls described in this Rule are meant to supplement, and not replace, the ETP Holder's own internal systems, monitoring and procedures related to risk management and are not designed for compliance

Timing and Implementation

The Exchange anticipates implementing the proposed change in the first quarter of 2024 and, in any event, will implement the proposed rule change no later than the end of June 2024. The Exchange will announce the timing of such changes by Trader Update.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed additional Pre-Trade Risk Controls would provide Entering Firms and Clearing Firms with enhanced abilities to manage their risk with respect to orders on the Exchange. The proposed additional Pre-Trade Risk Controls are not novel; they are based on existing risk settings already in place on MIAX Pearl and market participants are already familiar with the types of protections that the proposed risk controls afford.[10] As such, the Exchange believes that the proposed additional Pre-Trade Risk Controls would provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

In addition, the Exchange believes that the proposed rule change will protect investors and the public interest because the proposed additional Pre-Trade Risk Controls are a form of impact mitigation that will aid Entering Firms and Clearing Firms in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that ETP Holders implement a number of different risk-based controls, including those required by Rule 15c3–5. The controls proposed here will serve as an additional tool for Entering Firms and Clearing Firms to assist them in identifying any risk exposure. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's ETP Holders because use of the proposed additional Pre-Trade Risk Controls is optional and is not a prerequisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing Entering Firms and Clearing Firms additional means to monitor and control risk, the proposed rule will increase confidence in the proper functioning of the markets. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2024–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2024–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written

with Rule 15c3–5 under the Exchange Act. Responsibility for compliance with all Exchange and SEC rules remains with the ETP Holder.''

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See supra* note 6.

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(2)(B).

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENAT–2024–03, and should be submitted on or before March 27, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–04694 Filed 3–5–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

SBA Invention, Innovation, and Entrepreneurship Advisory Committee Meeting

AGENCY: Small Business Administration.

ACTION: Notice of Federal advisory committee meeting: SBA Invention, Innovation, and Entrepreneurship Advisory Committee.

SUMMARY: The U.S. Small Business Administration (SBA) will hold a virtual meeting of the SBA Invention, Innovation, and Entrepreneurship Advisory Committee on Tuesday, March 19, 2024. Members will convene as an independent source of advice and recommendations to SBA on matters supporting U.S. innovation, addressing commercialization hurdles and other vulnerabilities in the domestic investment and innovation ecosystem, and facilitating entrepreneurial access-to and participation-in federal innovation support and funding programs. The meeting will be virtual for members and streamed live to the public.

DATES: Tuesday, March 19, 2024, from 10:30 a.m. to 4:30 p.m. Eastern Time (ET).

ADDRESSES: The Invention, Innovation, and Entrepreneurship Advisory Committee will meet virtually and the meeting will be live streamed for the public. Register at *https://bit.ly/IIEAC-Mar19*.

FOR FURTHER INFORMATION CONTACT: Brittany Sickler, Designated Federal Officer, Office of Investment and Innovation, SBA, 409 3rd Street SW, Washington, DC 20416, (202) 369–8862 or *IIEAC@sba.gov*. The meeting will be live streamed to the public, and anyone wishing to submit questions to the SBA Invention, Innovation, and Entrepreneurship Advisory Committee can do so by submitting them via email to *IIEAC@sba.gov*. Individuals who require an alternative aid or service to communicate effectively with SBA should email the point of contact listed above and provide a brief description of their preferred method of communication.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the SBA Invention, Innovation, and Entrepreneurship Advisory Committee (the ''IIEAC''). The IIEAC is tasked with providingadvice, insights, and recommendations to SBA on matters broadly related to the U.S. startup and small business innovation ecosystem, and more specifically supporting innovation across the U.S.; developing and/or evolving SBA programs and services to address commercialization hurdles; addressing vulnerabilities and gaps in funding domestic invention and innovation; facilitating and enabling broad access and participation in federal innovation support and funding programs. The final agenda for the meeting will be posted on the IIEAC website at *https://www.sba.gov/about-sba/organization/sba-initiatives/invention-innovation-entrepreneurship-advisory-committee* prior to the meeting. Copies of the meeting minutes will be available by request within 90 days of the meeting date.

Public Comment

Any member of the public may submit pertinent questions and comments concerning IIEAC affairs at any time before or after the meeting and participate in the livestreamed meeting of the SBA Invention, Innovation, and Entrepreneurship Advisory Committee on March 19. Comments may be submitted to Brittany Sickler at *IIEAC@sba.gov*. Those wishing to participate live are encouraged to register by or before March 12, 2024, using the registration link provided above. Advance registration is strongly encouraged.

Dated: February 29, 2024.

Andrienne Johnson,

SBA Committee Management Officer.

[FR Doc. 2024–04673 Filed 3–5–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12353]

Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement

ACTION: Notice.

SUMMARY: A determination has been made that a number of foreign persons have engaged in activities that warrant the imposition of measures pursuant to the Iran, North Korea, and Syria Nonproliferation Act (INKSNA).

DATES: These measures are effective February 27, 2024.

FOR FURTHER INFORMATION CONTACT: On general issues: Pam Durham, Office of Missile, Biological, and Chemical Nonproliferation, Bureau of International Security and Nonproliferation, Department of State, Telephone (202) 647–4930. For U.S. Government procurement ban issues: Eric Moore, Office of the Procurement Executive, Department of State, Telephone: (703) 875–4079. Email: *mooreen@state.gov*.

SUPPLEMENTARY INFORMATION: The INKSNA provides for sanctions on foreign entities and individuals for the transfer to or acquisition from Iran since January 1, 1999; the transfer to or acquisition from Syria since January 1, 2005; or the transfer to or acquisition from the DPRK since January 1, 2006, of goods, services, or technology controlled under multilateral control lists (Australia Group, Chemical Weapons Convention, Missile Technology Control Regime, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems. The latter category includes: items of the same kind as those on multilateral lists but falling below the control list parameters when it is determined that such items have the potential of making

[14] 17 CFR 200.30–3(a)(12).

a material contribution to WMD or cruise or ballistic missile systems; items on U.S. national control lists for WMD/missile reasons that are not on multilateral lists; and other items with the potential of making such a material contribution when added through case-by-case decisions.

On February 27, 2024, the U.S. Government applied the measures authorized in section 3 of the Iran, North Korea, and Syria Nonproliferation Act (Pub. L. 109–353) against the following foreign persons identified in the report submitted pursuant to section 2(a) of the Act:

PMC Wagner; and any successor, sub-unit, or subsidiary thereof;

Pavel Shevelin (Russian individual);

LLC Eltekhnord and any successor, sub-unit, or subsidiary thereof;

Rim Yo'ng-hyo'k (aka Rim Yong Hyok) (DPRK individual)

Russian Aerospace Forces (aka VKS); and any successor, sub-unit, or subsidiary thereof.

Accordingly, pursuant to section 3 of the Act, the following measures are imposed on these persons:

1. No department or agency of the U.S. Government may procure or enter into any contract for the procurement of any goods, technology, or services from these foreign persons, except to the extent that the Secretary of State otherwise may determine;

2. No department or agency of the U.S. Government may provide any assistance to these foreign persons, and these persons shall not be eligible to participate in any assistance program of the U.S. Government, except to the extent that the Secretary of State otherwise may determine;

3. No U.S. Government sales to these foreign persons of any item on the United States Munitions List are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Control Reform Act of 2018 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the U.S. Government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise. These measures are independent of and in addition to any other sanctions imposed on such entities and/or individuals by other Federal agencies under separate legal authorities.

Ann K. Ganzer,

Acting Assistant Secretary for International Security and Nonproliferation, Department of State.

[FR Doc. 2024–04647 Filed 3–5–24; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Meeting of the National Parks Overflights Advisory Group

ACTION: Notice of meeting.

SUMMARY: The Federal Aviation Administration (FAA) and the National Park Service (NPS), in accordance with the National Parks Air Tour Management Act of 2000, announce the next meeting of the National Parks Overflights Advisory Group (NPOAG). This notification provides the date, location, and agenda for the meeting.

DATES: The NPOAG will meet on April 10–11, 2024. The meeting will take place in Conference Center Room 207 at the Volpe Center, 220 Binney St., Cambridge, MA. The meeting will be held from 8:30 a.m. to 5:00 p.m. on April 10, 2024, and from 8:30 a.m. to 12:30 p.m. on April 11, 2024. This NPOAG meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Sandra Fox, *sandra.y.fox@faa.gov;* (202)–267–0928; 800 Independence Ave. SW, Suite 900W, Washington, DC 20591.

SUPPLEMENTARY INFORMATION: The National Parks Air Tour Management Act of 2000 (NPATMA), enacted on April 5, 2000, as Public Law 106–181, required the establishment of the NPOAG within one year after its enactment. The Act requires that the NPOAG be a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairperson of the advisory group.

The duties of the NPOAG include providing advice, information, and recommendations to the FAA Administrator and the NPS Director on; implementation of Public Law 106–181; quiet aircraft technology; other measures that might accommodate interests to visitors of national parks; and at the request of the Administrator and the Director, on safety, environmental, and other issues related to commercial air tour operations over national parks or tribal lands.

Agenda for the April 10–11, 2024, NPOAG Meeting

The agenda for the meeting will include, but is not limited to, an update on ongoing park specific air tour management plans or voluntary agreements, status of agency implementation of court approved plan/schedule, update on environmental review process and special purpose law consultations, and public comment review process.

Attendance at the Meeting and Submission of Written Comments

Although this is not a public meeting, interested persons may attend. Because seating is limited, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** no later than March 22, 2024, if you plan to attend so that meeting space may be made to accommodate all attendees. Written comments regarding the meeting will be accepted directly from attendees or may be sent to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Record of the Meeting

If you cannot attend the NPOAG meeting, a summary of the meeting will be made available under the NPOAG section of the FAA ATMP website at: *https://www.faa.gov/about/office_org/headquarters_offices/apl/aee/air_tour_management_plan* or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, on February 29, 2024.

Sandra Fox,

Environmental Protection Specialist, Office of Environment and Energy.

[FR Doc. 2024–04672 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[FAA Docket number: FAA–2024–0658]

NextGen Advisory Committee; Notice of Public Meeting

AGENCY: Federal Aviation Administration (FAA), Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice announces three meetings of the NextGen Advisory Committee (NAC).

DATES: The meetings will be held on March 21, July 11, and October 10, 2024, between 9 a.m.–2 p.m. eastern time. Request to attend the meeting virtually must be received by March 13, July 2, and October 2, 2024. Request for accommodations for a disability must be received by March 13, July 2, and October 2, 2024. Written materials requested to be reviewed by NAC Members before the meeting must be received no later than March 13, July 2, and October 2, 2024.

ADDRESSES: The meetings will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, with a virtual option. Virtual meeting information will be provided on the NAC internet website at least one week in advance of the meeting. Information on the NAC, including copies of previous meeting minutes, is available on the NAC internet website at *https://www.faa.gov/about/office_org/headquarters_offices/ang/nac/*. Members of the public who wish to observe the meeting virtually or in person must send the required information listed in the **SUPPLEMENTARY INFORMATION** section to *9-AWA-ANG-NACRegistration@faa.gov*.

FOR FURTHER INFORMATION CONTACT: Kimberly Noonan, NAC Coordinator, U.S. Department of Transportation, at *Kimberly.Noonan@faa.gov* or 202–267–3760. Any requests or questions not regarding attendance registration should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of Transportation established the NAC under agency authority in accordance with the provisions of the Federal Advisory Committee Act, as amended, Public Law 92–463, 5 U.S.C. ch. 10, to provide independent advice and recommendations to the FAA and to respond to specific taskings received directly from the FAA. The NAC recommends consensus-driven advice for FAA consideration relating to Air Traffic Management System modernization.

II. Agenda

At the meeting, the agenda will cover the following topics:

- NAC Chair's Report
- FAA Report
- NAC Subcommittee Chair's Report
- Risk and Mitigations update for the following focus areas: Data Communications, Performance Based Navigation, Surface and Data Sharing, and Northeast Corridor
- NAC Tasking 23–2: National Airspace System (NAS) Airspace Efficiencies
- NAC Chair Closing Comments

The detailed agenda will be posted on the NAC internet website at least one week in advance of the meeting.

III. Public Participation

The meeting is open to the public. Members of the public who wish to attend are asked to register via email by submitting their full legal name, country of citizenship, contact information (telephone number and email address), and name of their industry association or applicable affiliation, and if they would like to attend the meeting in person or virtually. Please email this information to the email address listed in the **ADDRESSES** section. When registration is confirmed, registrants who requested to attend virtually will be provided the virtual meeting information/teleconference call-in number and passcode. Callers are responsible for paying associated long-distance charges (if any).

Note: Only NAC Members, NAC working group members, FAA staff who are providing briefings, and members of the public who registered and were selected to make a public statement will have the ability to speak. All other attendees will be able to listen only.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Any member of the public may present a written statement to the committee at any time. Written statements submitted by the deadline will be provided to the NAC members before the meeting. Written statements must be submitted to the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. Comments received after the due date listed in the **DATES** section will be distributed to the members but may not be reviewed prior to the meeting.

Signed in Washington, DC.

Kimberly Noonan,

Manager, Office of Stakeholder Collaboration, Management Services Office, ANG–A, Office of the Assistant Administrator for NextGen, Federal Aviation Administration.

[FR Doc. 2024–04651 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2023–1341]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Competition Plans, Passenger Facility Charges

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 23, 2023 under docket number FAA–2020–0385. The collection involves information on the availability of airport gates and related facilities, leasing and sub-leasing arrangements, gate-use requirements, gate-assignment policy, financial constraints, airport controls over air- and ground-side capacity, and whether the airport intends to build or acquire gates that would be used as common facilities. The information to be collected is necessary because it is required by statute that a covered airport submits a written competition plan to the Secretary/Administrator in order to receive approval to impose a Passenger Facility Charge (PFC) or to receive a grant under the Airport Improvement Program (AIP) or Bipartisan Infrastructure Law (BIL).

DATES: Written comments should be submitted by April 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Jane Johnson by email at: *jane.johnson@faa.gov;* phone: 202–267–5878.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the

estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0661.

Title: Competition Plans, Passenger Facility Charge.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 23, 2023 (88 FR 41184). This collection asks the public agencies to report on the availability of airport gates and related facilities, leasing and sub-leasing arrangements, gate-use requirements, gate-assignment policy, financial constraints, airport controls over air- and ground-side capacity, and whether the airport intends to build or acquire gates that would be used as common facilities. The DOT/FAA uses information submitted in response to this requirement to carry out the intent of §§ 40117(k) and 47106(f), which is to assure that a covered airport has, and implements, a plan to provide opportunities for competitive access by new entrant air carriers or air carriers seeking to expand. The information allows FAA to assess the competitive environment at airports and provide feedback to the airport on suggested improvements.

Once an airport qualifies as covered the collection frequency is as follows: it is required to send its initial competition plan as soon as possible. Upon approval by the FAA of the initial competition plan, the public agency must submit two (2) competition plan updates, in 18-month intervals, while it remains a covered airport. Once an airport has submitted, and the FAA has approved, its initial competition plan and the subsequent two (2) updates, a competition plan is only required if the airport (1) has filed a competitive access report as required by Section 424 of Vision 100, codified as 49 U.S.C. 47107(s) stating it has denied access to an air carrier for gates or facilities within the last six months; or (2) is executing a new master lease and use agreement, or significantly amending a lease and use agreement, including an amendment due to use of PFC financing of gates. If an airport loses its status as a covered airport, no further competition plan updates are required unless or until the airport becomes covered again.

Respondents: Five (5) affected airports annually.

Frequency: On occasion.

Estimated Average Burden per Response: Approximately 150 hours.

Estimated Total Annual Burden: Approximately 750 annually.

Issued in Washington, DC, on February 29, 2024.

David F. Cushing,

Manager, Airports Financial Assistance Division, APP–500.

[FR Doc. 2024–04681 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0054]

Request for Information on the J3400 Connector and Potential Options for Performance-Based Charging Standards

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; request for information (RFI).

SUMMARY: The FHWA issued regulations establishing minimum standards and requirements for certain electric vehicle (EV) chargers. Subsequent to the publication of this final rule, the Society of Automotive Engineers (SAE) published a Technical Information Report for a new connector standard, known as J3400, which multiple automakers have announced an intention to adopt in the coming years. To ensure the effective implementation of programs that are subject to the minimum standards and requirements and to inform a potential update to the minimum standards, FHWA, in coordination with the Joint Office of Energy and Transportation, is seeking additional information in five areas: on the expectations surrounding market availability for J3400 within EVs and EV chargers; on the technical compatibility of J3400 with existing regulations and safety considerations; on considerations regarding challenges and benefits of the implementation of J3400 at charging stations; on market demands for the continued availability of Combined Charging System (CCS) and J1772 connectors; and potential options for performance-based standards that can reduce the need for future regulatory updates or changes as technology evolves.

DATES: Comments must be received on or before April 5, 2024. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit comments by only one of the following means:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments;
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329;
- *Instructions:* You must include the agency name and docket number at the beginning of your comments. Except as described below under the heading ''Confidential Business Information,'' all submissions received, including any personal information provided, will be posted without change or alteration to *www.regulations.gov.* For more information, you may review the U.S. Department of Transportation's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Ms. Suraiya Motsinger, FHWA Office of Natural Environment, (202) 366–4287, or via email at *suraiya.motsinger@dot.gov.* For legal questions, please contact Ms. Dawn Horan, FHWA Office of the Chief Counsel, (202) 366–9615, or via email at *Dawn.M.Horan@dot.gov.* Office hours for FHWA are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

A copy of this notice, all comments received on this notice, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval assistance and guidelines are also available at *www.regulations.gov.* An electronic copy of this document also may be downloaded from the Office of the Federal Register's website at: *www.FederalRegister.gov* and the U.S. Government Publishing Office's website at: *www.GovInfo.gov.*

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial

information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI.

You may ask FHWA to give confidential treatment to information you give to the Agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send FHWA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. The FHWA will protect confidential information complying with these requirements to the extent required under applicable law. Information collected in this RFI may also be shared with the Joint Office of Energy and Transportation and Department of Energy (DOE) consistent with Congressional direction that the minimum standards and requirements for EV chargers be developed in coordination with DOE. The Joint Office of Energy and Transportation will protect any such shared information in accordance with applicable DOE standards. If DOT receives a FOIA request for the information that the applicant has marked in accordance with this notice, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.29. Only information that is marked in accordance with this notice and ultimately determined to be exempt from disclosure under FOIA and 49 CFR 7.29 will not be released to a requester or placed in the public docket of this notice. Submissions containing CBI should be sent to: Ms. Suraiya Motsinger, FHWA, 1200 New Jersey Avenue SE, HICP–20, Washington, DC 20590 via mail, or *suraiya.motsinger@dot.gov* via email. Any comment submissions that FHWA receives that are not specifically designated as CBI will be placed in the public docket for this matter.

Background

On February 28, 2023, FHWA published a final rule [1] establishing minimum standards and requirements for projects funded under the National Electric Vehicle Infrastructure (NEVI) Formula Program and projects for the construction of publicly accessible electric vehicle (EV) chargers that are funded with funds made available under Title 23, United States Code, including any EV charging infrastructure project funded with Federal funds that is treated as a project on a Federal-aid highway. As outlined in statute, the purpose of the NEVI Formula Program is to ''provide funding to States to strategically deploy EV charging infrastructure and to establish an interconnected network to facilitate data collection, access, and reliability.'' This purpose is satisfied by creating a convenient, affordable, reliable, and equitable network of chargers throughout the country. Prior to the establishment of this rule, there were no national standards for the installation, operation, or maintenance of EV charging stations, and wide disparities exist among EV charging stations. The final rule enables States or other designated recipients to implement federally funded charging station projects in a standardized fashion in order to build a convenient, accessible, reliable, and equitable charging network across the country that can be utilized by all EVs regardless of vehicle brand. Such standards provide reliable expectations for travel in an EV across and throughout the United States.

As part of this rule, FHWA regulates the connector type used on EV chargers through 23 CFR 680.106(c) which states, ''All charging connectors must meet applicable industry standards. Each Direct Current Fast Charger (DCFC) charging port must be capable of charging any Combined Charging System (CCS)-compliant vehicle and each DCFC charging port must have at least one permanently attached CCS Type 1 connector. In addition, permanently attached CHAdeMO (*www.chademo.com*) connectors can be provided using only FY2022 NEVI Funds. Each Alternating Current (AC) Level 2 charging port must have a permanently attached J1772 connector and must charge any J1772-compliant vehicle.'' The final rule allows permanently attached non-proprietary connectors to be provided on each charging port so long as each DCFC charging port has at least one permanently attached CCS Type 1 connector and is capable of charging a CCS-compliant vehicle.

Subsequent to the publication of 23 CFR part 680, the Society of Automotive Engineers (SAE) published a Technical Information Report (TIR) [2] in December 2023 which provided information on the J3400 EV charging connector standard (also known as the North American Charging Standard Electric Vehicle Coupler). J3400 utilizes the same connector and pins for AC and DC charging; the publication of a new connector standard has implications for both vehicles and chargers. To date, J3400 has only been utilized in a proprietary implementation by one auto manufacturer and its charging network. However, several additional auto manufacturers have announced an intention to adopt J3400 with full vehicular integration beginning in 2025, and through adapters as early as 2024. Multiple charging equipment manufacturers have also publicly committed to adopting the J3400 connector on chargers. The FHWA, in coordination with the Joint Office of Energy and Transportation, seeks information to better understand how the introduction and adoption of J3400 will impact the EV charging industry, automakers, and EV charging consumers and to inform potential updates to the minimum standards.

To ensure FHWA has the most comprehensive and current information available, FHWA is specifically seeking detailed comments on the expectations surrounding market availability for J3400 within EVs and EV chargers, on the technical compatibility of J3400 with existing regulations, on considerations regarding challenges and benefits of the implementation of J3400 at charging stations, on market demands for the continued availability of CCS and J1772 connectors, and on potential options for performance-based standards that can reduce the need for future regulatory updates or changes as technology evolves. The FHWA is also interested in obtaining more information on the impact of the publication of the J3400 TIR in order to assess how the minimum standards and requirements for EV charging can address the evolving needs of EV charging consumers and industry.

The FHWA additionally requests information on what performance-based standards would best facilitate competition and innovation in EV markets, consistent with the Office of Information and Regulatory Affairs ''Guidance on Accounting for

[1] On November 15, 2021, the Bipartisan Infrastructure Law (BIL) was enacted as the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58. To ensure standardization for a nationwide network of EV chargers, the BIL mandated the creation of a set of minimum standards and requirements for electric vehicle chargers which were finalized under 23 CFR 680 by FHWA on February 28, 2023, at 88 FR 12724.

[2] *https://www.sae.org/news/2023/12/sae-j3400-tir-released.*

Competition Effects When Developing and Analyzing Regulatory Actions.'' [3] The term ''performance-based standards'' in this context refers to standards that specify a level of service and types of vehicles a charger must support without specifying specific connectors.

Request for Comments and Information

To ensure the effective implementation of programs that are subject to the minimum standards and requirements, FHWA requests information from the public, auto manufacturers, charger manufacturers, and others involved with or impacted by EV charging regarding the impact of the publication of the J3400 TIR. The FHWA is seeking additional information in five areas: (1) on the expectations surrounding market availability for J3400 within EVs and EV chargers, (2) on the technical compatibility of J3400 with existing regulations and safety considerations, (3) on considerations regarding challenges and benefits of the implementation of J3400 at charging stations, (4) on market demands for the continued availability of CCS and J1772 connectors, and (5) on options for performance-based standards.

1. Market Availability

a. What is the expected commercial availability and timeframe of J3400 EVSE products such as connector and cable assemblies, EV chargers, and adapters? Please be as specific (to month/year, anticipated volumes) as possible.

b. What safety standards will J3400 EVSE products need to be certified to and when will that certification occur? Are there any concerns with obtaining appropriate electrical and mechanical safety certifications for the J3400 connector?

c. What is the commercial availability and timeframe of vehicles with (i) J3400 inlets, and (ii) 800V system architecture? Please be as specific (to month/year, anticipated volumes) as possible.

d. Will future 800V vehicles be backwards compatible with 400V charging stations? If yes, for how long?

e. What, if any, opportunities do you see to commercial availability and use of J3400 connectors and chargers?

f. What, if any, barriers do you see to commercial availability and use of J3400 connectors and chargers?

g. Is there existing domestic manufacturing capacity to meet anticipated demand for J3400 connectors and chargers? If not, when do you expect this capacity to be available? How many companies have capability to ramp up production of J3400 ports, connectors, and/or adapters?

h. How might the ownership and exercise of intellectual property rights impact the development of J3400 EVSE products?

2. Technical Compatibility With 23 CFR Part 680

a. Do you foresee any challenges with J3400 specifically meeting the power delivery requirements in 23 CFR 680.106(d)? Please elaborate on these challenges with specific examples, data, etc.

b. Do you foresee any challenges with J3400 specifically meeting the interoperability requirements in 23 CFR 680.108? Are there any challenges with J3400 meeting other aspects of interoperability, including compatibility, safety, and performance of connectors/inlets/adapters, communications or security protocols, or support of vehicles designed to charge using CCS/J1772 connectors? Please elaborate on these challenges with specific examples, data, etc.

c. Do you foresee any other challenges with J3400 meeting other existing requirements in 23 CFR part 680? Please elaborate on these challenges with specific examples, data, etc.

d. Have any issues been identified or foreseen using a combined connector that accommodates both CCS Type 1 and J3400 connectors with one cable (as an example, combined connector designs such as Tesla's Magic Dock)? Is there a difference in performance or durability between the use of a combined cable with multiple connectors and the use of two separate cables (each with their own connector)? Please comment specifically about power level and reliability.

3. Implementation Challenges and Benefits at Charging Stations

a. Is there a need to include J3400 connectors on all federally-funded chargers? Is there a difference between the use of J3400 connectors for DCFC or AC Level 2 charging?

b. Is it practical to retrofit an existing DCFC with a J3400 or other connector either in addition or as a replacement to an existing connector? What is the cost of installation to retrofit an existing charger with a J3400 or other connector in addition or as a replacement to an existing connector? Would retrofitted or added J3400 connectors on DCFC ports suffer from performance loss relative to natively installed CCS connectors? Are there other challenges with retrofitting an existing charger? If so, please describe challenges.

c. What is the cost of a DCFC with a CCS Type 1 connector? What is the anticipated cost of a DCFC with a J3400 connector? What is the anticipated cost of a charger that provides both CCS Type 1 and J3400 at each port? Are there differences in maintenance considerations between these different types of DCFCs?

d. What is the cost of an AC Level 2 charger with a J1772 connector? What is the anticipated cost of an AC Level 2 charger with a J3400 connector? What is the anticipated cost of a charger that provides both J1772 and J3400? Are there differences in maintenance considerations between these different types of AC Level 2 chargers?

e. What, if any, equity-related challenges or benefits may result from use of J3400 connectors? What are the benefits or challenges for persons with disabilities between using J3400 and CCS/J1772 connectors? What strategies could increase those benefits or mitigate the challenges? If each charging station has a specified number of each type of connector (J3400 and CCS Type 1/ J1772), should accessible spots be required to have both connectors?

f. What are workforce needs associated with retrofitting or installing chargers to be J3400 compatible and maintaining those chargers once installed? Will existing training and certification programs need to be updated or amended to cover J3400 installation, operations, and maintenance?

g. Are there any compatibility, reliability, or safety concerns about charging vehicles that are designed to charge using CCS/J1772 connectors at new J3400 AC level 2 chargers or at J3400 DCFCs with an adapter?

h. What are the challenges, if any, in ensuring that J3400 will utilize ISO15118 cyber physical security protections such as TLS authorization and authentication?

4. Market Demands for the Continued Availability of CCS, J1772, and J3400 Connectors

a. Over time, what will be the expected continued demand for CCS/ J1772 connectors?

b. Over time, what will be the expected market adoption of J3400 in new vehicle models? Please be specific in regard to the anticipated percentage of J3400 and CCS/J1772 vehicles by model year.

c. Over time, what will be the expected demand for J3400 connectors?

[3] *https://www.whitehouse.gov/wp-content/uploads/2023/10/RegulatoryCompetitionGuidance.pdf.*

Are new connector types (other than CCS, J1772, and J3400) likely to enter the market?

d. What is the anticipated useful life of the CCS, J1772, and J3400 connectors and cables that are currently in use (or that will be installed in the near future)?

e. What is the expected impact of the TIR to the market for vehicle models that were manufactured to utilize CCS/J1772 connectors?

5. Performance-Based Standards [4]

a. If there is a need to include J3400 connectors on chargers, what are the advantages and disadvantages of the following design-based approaches?

Approach 1: Include both J3400 and CCS Type 1/J1772 connectors on each port.

Approach 2: Include a specified number of each type of connector (J3400 and CCS Type 1/J1772) at each charging station.

Under Approach 2, what is the optimal ratio of J3400 connectors to CCS/J1772 connectors? Why?

If there is not a need to include J3400 connectors on chargers, what are the advantages and disadvantages of the following design-based approaches to including J3400, CCS/J1772, or other connectors alongside cables?

Approach 1: Provide at least one adapter for J3400 connectors at each charging station.

Approach 2: Customers must provide their own adapters for use.

Are there alternative design-based approaches to accommodate J3400 and CCS/J1772 equipped vehicles?

b. Are there performance-based alternatives to specifying charging standards and communication standards (such as J3400, J1772, or ISO 15118) by reference that would support a convenient, affordable, reliable, and equitable EV charging network while reducing the need for future refinement to federal regulations?

c. Which performance-based alternative (*i.e.,* standards that specify a level of service and types of vehicles a charger must support without specifying specific connectors) would best facilitate competition and innovation in EV markets? Which performance-based alternatives have the potential to harm competition, create consumer lock in, or otherwise erect or increase entry barriers?

d. Should performance-based standards include requirements for achieving Key Performance Indicators most important to EV customers? If so, what should those Key Performance Indicators be?

6. Other Considerations

a. Is there anything additionally that should be considered related to EV charging connector standards and technologies that is not covered in the above questions?

b. Are there any supply chain issues for EVs and EVSEs related to support for 800V architectures?

Shailen P. Bhatt,

Administrator, Federal Highway Administration.

[FR Doc. 2024–04750 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–22–P

[4] As noted above, the term ''performance-based standards'' in this context refers to standards that specify a level of service and types of vehicles a charger must support without specifying specific connectors.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT–OST–2024–0030]

Advisory Committee on Transportation Equity (ACTE); Notice of Public Meeting

AGENCY: Office of the Secretary, Department of Transportation

ACTION: Notice of public meeting.

SUMMARY: DOT OST announces a virtual meeting of ACTE's Power of Community Subcommittee, which will take place via Zoom Webinar.

DATES: The meeting will be held Tuesday, March 26, 2024, from 12:00 to 2:00 p.m. Eastern Time. Requests for accommodations because of a disability must be received by Tuesday, March 19. Requests to submit questions must be received no later than Tuesday, March 19. The registration form will close on Monday, March 25.

ADDRESSES: The meeting will be held via Zoom webinar. Those members of the public who would like to participate virtually should go to *https://www.transportation.gov/mission/civil-rights/advisory-committee-transportation-equity-meetings-materials* to access the meeting, a detailed agenda for the entire meeting, meeting minutes, and additional information on ACTE and its activities.

FOR FURTHER INFORMATION CONTACT: Sandra D. Norman, Senior Advisor and Designated Federal Officer, Departmental Office of Civil Rights, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (804) 836–2893, *ACTE@dot.gov.* Any ACTE-related request or submissions should be sent via email to the point of contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Purpose of the Committee

ACTE was established to provide independent advice and recommendations to the Secretary of Transportation about comprehensive, interdisciplinary issues related to civil rights and transportation equity in the planning, design, research, policy, and advocacy contexts from a variety of transportation equity practitioners and community leaders. Specifically, the Committee will provide advice and recommendations to inform the Department's efforts to:

Implement the Agency's Equity Action Plan and Strategic Plan, helping to institutionalize equity into Agency programs, policies, regulations, and activities;

Strengthen and establish partnerships with overburdened and underserved communities who have been historically underrepresented in the Department's outreach and engagement, including those in rural and urban areas;

Empower communities to have a meaningful voice in local and regional transportation decisions; and

Ensure the compliance of Federal funding recipients with civil rights laws and nondiscrimination programs, policies, regulations, and activities.

Meeting Agenda

The agenda for the meeting will consist of:

Welcome and Introductions
History of ACTE
Scope of Power of Community Subcommittee
Review of existing recommendations
Public engagement open discussion
Next steps and closing remarks
Meeting Participation

Advance registration is required. Please register at *https://usdot.zoomgov.com/webinar/register/WN_7LmQxZGmQCmO3V9UQpL-WQ* by the deadline referenced in the **DATES** section. The meeting will be open to the public for its entirety. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section. Questions from the public will be answered during the public comment period only at the discretion of the ACTE Wealth Creation subcommittee co-chairs and designated Federal officer. Members of the public may submit written comments and

questions to the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section on the topics to be considered during the meeting by the deadline referenced in the **DATES** section.

Dated: February 29, 2024.

Irene Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2024–04689 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT–OST–2024–0029]

Advisory Committee on Transportation Equity (ACTE); Notice of Public Meeting

AGENCY: Office of the Secretary, Department of Transportation

ACTION: Notice of public meeting.

SUMMARY: DOT OST announces a virtual meeting of ACTE's Expanding Access Subcommittee, which will take place via Zoom Webinar.

DATES: The meeting will be held Thursday, March 21, 2024, from 2:00 to 4:00 p.m. Eastern Time. Requests for accommodations because of a disability must be received by Thursday, March 14. Requests to submit questions must be received no later than Thursday, March 14. The registration form will close on Wednesday, March 20.

ADDRESSES: The meeting will be held via Zoom Webinar. Those members of the public who would like to participate virtually should go to *https://www.transportation.gov/mission/civil-rights/advisory-committee-transportation-equity-meetings-materials* to access the meeting, a detailed agenda for the entire meeting, meeting minutes, and additional information on ACTE and its activities.

FOR FURTHER INFORMATION CONTACT: Sandra D. Norman, Senior Advisor and Designated Federal Officer, Departmental Office of Civil Rights, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (804) 836–2893, *ACTE@dot.gov.* Any ACTE-related request or submissions should be sent via email to the point of contact listed above.

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Strengthen and establish partnerships with overburdened and underserved communities who have been historically underrepresented in the Department's outreach and engagement, including those in rural and urban areas;

Empower communities to have a meaningful voice in local and regional transportation decisions; and

Ensure the compliance of Federal funding recipients with civil rights laws and nondiscrimination programs, policies, regulations, and activities.

Meeting Agenda

The agenda for the meeting will consist of:

Welcome and Introductions
History of ACTE
Scope of Expanding Access Subcommittee
Review of existing recommendations
Public engagement open discussion
Next steps and closing remarks
Meeting Participation

Advance registration is required. Please register at *https://usdot.zoomgov.com/webinar/register/WN_hpw_gqNRQOaPA-C1Zs3vyA* by the deadline referenced in the **DATES** section. The meeting will be open to the public for its entirety. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section. Questions from the public will be answered during the public comment period only at the discretion of the ACTE Wealth Creation subcommittee co-chairs and designated Federal officer. Members of the public may submit written comments and questions to the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section on the topics to be considered during the meeting by the deadline referenced in the **DATES** section.

Dated: February 29, 2024.

Irene Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2024–04684 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT–OST–2024–0031]

Advisory Committee on Transportation Equity (ACTE); Notice of Public Meeting

AGENCY: Office of the Secretary, Department of Transportation

ACTION: Notice of public meeting.

SUMMARY: DOT OST announces a virtual meeting of ACTE's Interventions Subcommittee, which will take place via Zoom Webinar.

DATES: The meeting will be held Wednesday, March 27, 2024, from 12 to 2 p.m. eastern time. Requests for accommodations because of a disability must be received by Wednesday, March 20. Requests to submit questions must be received no later than Wednesday, March 20. The registration form will close on Tuesday, March 26.

ADDRESSES: The meeting will be held via Zoom Webinar. Those members of the public who would like to participate virtually should go to *https://www.transportation.gov/mission/civil-rights/advisory-committee-transportation-equity-meetings-materials* to access the meeting, a detailed agenda for the entire meeting, meeting minutes, and additional information on ACTE and its activities.

FOR FURTHER INFORMATION CONTACT: Sandra D. Norman, Senior Advisor and Designated Federal Officer, Departmental Office of Civil Rights, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (804) 836–2893, *ACTE@dot.gov.* Any ACTE-related request or submissions should be sent via email to the point of contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Purpose of the Committee

ACTE was established to provide independent advice and recommendations to the Secretary of Transportation about comprehensive, interdisciplinary issues related to civil rights and transportation equity in the planning, design, research, policy, and advocacy contexts from a variety of transportation equity practitioners and community leaders. Specifically, the

Committee will provide advice and recommendations to inform the Department's efforts to:

Implement the Agency's Equity Action Plan and Strategic Plan, helping to institutionalize equity into Agency programs, policies, regulations, and activities;

Strengthen and establish partnerships with overburdened and underserved communities who have been historically underrepresented in the Department's outreach and engagement, including those in rural and urban areas;

Empower communities to have a meaningful voice in local and regional transportation decisions; and

Ensure the compliance of Federal funding recipients with civil rights laws and nondiscrimination programs, policies, regulations, and activities.

Meeting Agenda

The agenda for the meeting will consist of:

Welcome and Introductions
History of ACTE
Scope of the Interventions
Subcommittee
Review of existing recommendations
Public engagement open discussion
Next steps and closing remarks
Meeting Participation

Advance registration is required. Please register at *https://usdot.zoomgov.com/webinar/register/WN_VJdU3tfxRqeD-FC4KEkPEw* by the deadline referenced in the **DATES** section. The meeting will be open to the public for its entirety. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section. Questions from the public will be answered during the public comment period only at the discretion of the ACTE Wealth Creation subcommittee co-chairs and designated Federal officer. Members of the public may submit written comments and questions to the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section on the topics to be considered during the meeting by the deadline referenced in the **DATES** section.

Dated: February 29, 2024.

Irene Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2024–04687 Filed 3–5–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request Relating to Product Liability Losses and Accumulations for Product Liability Losses

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Product Liability Losses and Accumulations for Product Liability Losses.

DATES: Written comments should be received on or before May 6, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Please include OMB Number 1545–0863 or TD 8096 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the should be directed to Sara Covington, at (202) 317–5744 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Sara.L.Covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Product Liability Losses and Accumulations for Product Liability Losses.

OMB Number: 1545–0863.

Regulation Project Number: T.D. 8096.

Abstract: T.D. 8096 provides final regulations relating to product liability losses and accumulations for the payment of reasonable anticipated product liability losses. Changes to the applicable tax law were made by the Revenue Act of 1978. Generally, a taxpayer who sustains a product liability loss must carry the loss back 10 years. However, a taxpayer may elect to have such loss treated as a regular net operating loss under section 172. If desired, such election is made by attaching a statement to the tax return. This statement will enable the IRS to monitor compliance with the statutory requirements.

Current Actions: There is no change to this existing regulation or to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 2,500.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 29, 2024.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2024–04677 Filed 3–5–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Refunds and Credits; Periods of Limitations; Financial Disability

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Refunds and Credits; Periods of Limitations; Financial Disability.

DATES: Written comments should be received on or before May 6, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224 or by email to *pra.comments@irs.gov.* Please include the OMB Control Number 1545–1649 or Revenue Procedure 99–21 in the Subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Sara Covington, at (202) 317–5744 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *sara.l.covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Refunds and Credits; Periods of Limitations; Financial Disability.

OMB Number: 1545–1649.

Revenue Procedure: Revenue Procedure 99–21.

Abstract: Generally, under section 6511(a), a taxpayer must file a claim for credit or refund of tax within three years after the date of filing a tax return or within two years after the date of payment of the tax, whichever period expires later. Under section 6511(h), the statute of limitations on claims for credit or refund is suspended for any period of an individual taxpayer's life during which the taxpayer is unable to manage his or her financial affairs because of a medically determinable mental or physical impairment, if the impairment can be expected to result in death, or has lasted (or can be expected to last) for a continuous period of not less than 12 months.

Current Actions: There is no change in the paperwork burden previously approved by OMB. The revenue procedure is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 48,200.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 24,100.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 29, 2024.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2024–04676 Filed 3–5–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Credit for Increasing Research Activities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning credit for increasing research activities.

DATES: Written comments should be received on or before May 6, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Include OMB control number 1545–0619 or Credit for Increasing Research Activities.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Credit for Increasing Research Activities.

OMB Number: 1545–0619.

Form Number: 6765.

Abstract: Internal Revenue Code section 38 allows a credit against income tax (Determined under IRC section 41) for an increase in research activities in a trade or business. Form 6765 is used by businesses and individuals engaged in a trade or business to figure and report the credit. The data is used to verify that the credit claimed is correct.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, and not-for-profit institutions.

Estimated Number of Respondents: 15,805.

Estimated Time per Respondent: 18 hours, 2 minutes.

Estimated Total Annual Burden Hours: 285,281 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 28, 2024.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2024–04760 Filed 3–5–24; 8:45 am]

BILLING CODE 4830–01–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open public hearing.

SUMMARY: Notice is hereby given of the following hearing of the U.S.-China Economic and Security Review Commission. The Commission is mandated by Congress to monitor, investigate, and report to Congress annually on ''the national security implications of the economic relationship between the United States and the People's Republic of China.'' Pursuant to this mandate, the Commission will hold a public hearing in Washington, DC on March 21, 2024 on ''China's Evolving Counter Intervention Capabilities and Implications for the U.S. and Indo-Pacific Allies and Partners.''

DATES: The hearing is scheduled for Thursday, March 21, 2024 at 9:30 a.m.

ADDRESSES: Members of the public will be able to attend in person at a location TBD or view a live webcast via the Commission's website at *www.uscc.gov. Visit the Commission's website for updates to the hearing location or possible changes to the hearing schedule. Reservations are not required to view the hearing online or in person.*

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Jameson Cunningham, 444 North Capitol Street NW, Suite 602, Washington DC 20001; telephone: 202–624–1496, or via email at *jcunningham@uscc.gov. Reservations are not required to attend the hearing.*

ADA Accessibility: For questions about the accessibility of the event or to request an accommodation, please contact Jameson Cunningham via email at *jcunningham@uscc.gov.* Requests for an accommodation should be made as soon as possible, and at least five business days prior to the event.

SUPPLEMENTARY INFORMATION:

Background: This is the third public hearing the Commission will hold during its 2024 reporting cycle. The hearing will begin with an assessment of China's capabilities and concepts to prevent, block, or blunt U.S. military actions in the Indo-Pacific. Next it will examine U.S. efforts to contest and defeat China's counter-intervention capabilities with a focus on China's perception of those efforts. Finally, it will consider the perspectives and strategies of key U.S. allies including Japan, the Philippines, and Australia on China's military capabilities and the implications for regional security architecture.

The hearing will be co-chaired by Vice Chair Reva Price and Commissioner Randall Schriver. Any interested party may file a written statement by March 21, 2024 by transmitting it to the contact above. A portion of the hearing will include a question and answer period between the Commissioners and the witnesses.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005), as amended by Public Law 113–291 (December 19, 2014).

Dated: March 1, 2024.

Christopher Fioravante,

Director of Operations and Administration, U.S.-China Economic and Security Review Commission.

[FR Doc. 2024–04723 Filed 3–5–24; 8:45 am]

BILLING CODE 1137–00–P

DEPARTMENT OF VETERANS AFFAIRS

Geriatric and Gerontology Advisory Committee, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, FACA 5 U.S.C. ch. 10, that the Geriatric and Gerontology Advisory Committee will meet on April 10–11, 2024. The April meeting sessions will begin and end as follows:

Date	Time	Open session
April 10, 2024	8:30 a.m.–4:30 p.m. Eastern Daylight Time (EDT)	Yes.
April 11, 2024	8:30 a.m.–12:00 p.m. EDT	Yes.

This meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary of VA and the Under Secretary for Health on all matters pertaining to geriatrics and gerontology. The Committee assesses the capability of VA health care facilities and programs to meet the medical, psychological, and social needs of older Veterans, and evaluates VA programs designated as Geriatric Research, Education, and Clinical Centers.

Time will be allocated for receiving public comments on April 10, 2024, at

3:30 p.m. Individuals wishing to present public comments should contact Marianne Shaughnessy, Ph.D., AGPCNP–BC, GS–C, FAAN., Designated Federal Officer, Veterans Health Administration by email at *Marianne.Shaughnessy@va.gov* or at 202–407–6798 no later than close of business on March 22, 2024. Only those members of the public (first 6 public comment registrants) who have confirmed registrations to present public comment will be allowed to speak at this meeting. In the interest of time, each speaker will be held to 5-minute time limit. Individuals who are unable to attend but would like to have comment included in the meeting record may send them to *Marianne.Shaughnessy@va.gov* by close of business on March 29, 2024. All individuals wishing to present public comments must provide a written summary of the comment for inclusion in the meeting record that includes name and organization/association of persons they represent.

Any member of the public wishing to attend virtually or seeking additional information should email *Marianne.Shaughnessy@va.gov* or call 202–407–6798, no later than close of business on March 27, 2024, to provide their name, professional affiliation, email address and phone number. The WebEx link for April 10, 2024: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m73491837bf953288b898b684d8556b10,* meeting number (access code): 2762 065 0269, meeting password: wXUqC8mk@22. On April 11, 2024:, the WebEx link is: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m01aa0a5e4dafba6407c8cba0ccd7c930,* meeting number (access code): 2761 220 7733, meeting password: 4pkWPp9hP3@o or to join by phone either day dial: 1–404–397–1596.

Dated: March 1, 2024.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–04706 Filed 3–5–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Wednesday,

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Part II

Department of Agriculture

Agricultural Marketing Service

9 CFR Part 201

Inclusive Competition and Market Integrity Under the Packers and Stockyards Act; Final Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

9 CFR Part 201

[Doc. No. AMS–FTPP–21–0045]

RIN 0581–AE05

Inclusive Competition and Market Integrity Under the Packers and Stockyards Act

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The U.S. Department of Agriculture's (USDA or Department) Agricultural Marketing Service (AMS or the Agency) amends its Packers and Stockyards Act, 1921, regulations to prohibit undue prejudice and unjust discrimination against individuals on a prohibited basis unrelated to the quality of the service or product provided. The rule also identifies retaliatory practices that interfere with lawful communications, assertion of rights, and associated participation, among other protected activities, as unjust discrimination prohibited by the law. Finally, the rule identifies deceptive practices that violate the Packers and Stockyards Act with respect to contract formation, contract performance, contract termination, and contract refusal. The purpose of this rule is to promote inclusive competition and market integrity in the livestock, meats, poultry, and live poultry markets.

DATES: This rule is effective May 6, 2024.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, USDA AMS Fair Trade Practices Program, 1400 Independence Ave. SW, Washington, DC 20250; Telephone: (202) 690–4355; or email: *s.brett.offutt@usda.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

The rise of concentration and changes in contracting practices in livestock and poultry markets over the last four decades have facilitated and exposed producers and growers (hereafter, producers unless otherwise noted) to increasing economic harms from exclusionary, prejudicial, or otherwise discriminatory conduct, as well as deceptive conduct, by packers, swine contractors, and live poultry dealers (hereinafter regulated entities, unless otherwise noted). The regulatory toolkit embodied in the Packers and Stockyards Act, 1921, as amended (P&S Act or the Act) (7 U.S.C. 181 *et seq.*), authorizes USDA to issue regulations to address these issues. This final rule seeks to address a discrete but important set of those wrongfully exclusionary or deceptive practices that undermine inclusive competition and market integrity: specifically, (1) discriminatory prejudices on certain bases relating to the producer's characteristics, (2) retaliation for engaging in certain acts as part of being a livestock or poultry producer or grower, and (3) false or misleading statements or material omissions in certain contexts. These practices deny producers opportunities to compete in the marketplace and earn the full value of their livestock sales or poultry growout services.

On October 3, 2022, AMS published in the **Federal Register** (87 FR 60010) a proposal to amend the regulations implementing the Act located in title 9, part 201, of the Code of Federal Regulations (CFR) by adding a new subpart O titled ''Competition and Market Integrity.'' AMS solicited comments on the proposed rule for an initial period of 60 days, and extended the comment period for an additional 45 days on November 30, 2022 (87 FR 73507). AMS received 446 comments from industry trade associations, non-profit organizations, individuals, State attorneys general, farm bureaus, academic/research institutions, and other groups. After consideration of all comments, AMS is adopting the proposed rule, with modifications designed to increase specificity and, therefore, certainty and enforceability.

AMS is issuing these regulations to enhance basic protections that modern livestock and poultry producers need to promote inclusive competition and market integrity. Specifically, this final rule will:

- Prohibit, as undue prejudices or disadvantages, actions that inhibit market access or actions that are otherwise adverse to covered producers on the basis of race, color, religion, national origin (including ethnicity), sex (including sexual orientation and gender identity, as well as pregnancy), disability, marital status, or age; or because of the covered producer's status as a cooperative, with certain narrow exceptions such as the provision of religious meats and the functions of Tribal governments;
- Prohibit, as unjust discrimination, retaliatory and adverse actions that interfere with lawful communications, assertion of rights, associational participation, and other protected activities;
- Prohibit, as deceptive practices, regulated entities employing false or misleading statements or omissions of material information in contract formation, performance, and termination; and prohibit regulated entities from providing false or misleading representations regarding refusal to contract; and
- Require recordkeeping to support USDA monitoring, evaluation, and enforcement of compliance with aspects of this rule.

AMS is adopting this final rule to promote inclusive competition and market integrity, as rational decision-making, so critical to economic success, can most effectively occur in a market free of the practices prohibited by this

rule. This final rule also affirms the importance of a clear and direct regulatory framework with respect to prohibited conduct, thus protecting producers in the marketplace. This rule does not address every possible way in which producers may be wrongfully excluded or deceived under the Act. Producers who believe their rights under the Act have been violated—whether specifically under this final rule, or in other circumstances—can report a violation to AMS.[1] For some matters in poultry, USDA further refers the case to the U.S. Department of Justice (DOJ) for enforcement.[2] Producers may also enforce the law and its regulations through private rights of action under the Act. Penalties under the Act depend upon the nature of the particular violation, including the particular animal species, and range from monetary penalties to injunctive relief.

This final rule is effective 60 days after publication in the **Federal Register**. AMS has chosen this effective date because it believes that compliance with this final rule will not require significant administrative or financial obligations for regulated entities. The low cost, coupled with minimal process changes regulated entities will be required to make to comply, support an effective date 60 days after publication. Sixty days will provide adequate time for regulated entities to be informed of the specified conduct this final rule prohibits as well as make changes to comply with the final rule.

II. Background

A. Current Market Structure and Risks for Producers

Market abuses of discrimination, retaliation, and deception can occur in livestock and poultry markets. Such conduct is amplified and exacerbated under increasingly concentrated livestock and poultry markets. Such markets are dominated by a few large packers and live poultry dealers. Additionally, changes in contracting practices, specifically bilateral contracting and vertical contracting that reaches farther into the production aspects of livestock and poultry, have given processors greater control over producers. These changes can exacerbate the impacts of discriminatory, retaliatory, and deceptive conduct by packers and live poultry dealers, which inhibits producers from fully participating in livestock and poultry markets or obtaining the full value of their livestock and poultry products and services. With few marketing options in concentrated markets, producers are more likely to suffer long lasting harm from market abuses by packers and live poultry dealers than would be the case in a marketplace that is more competitive.

A review of the historical structure of livestock and poultry markets shows how the risk of worsened competitive conditions or materially adverse effects to producers at the hands of a few large processors (livestock packers and live poultry dealers) has grown over time. In the late 1800s to early 1900s, the ''Big Five'' [3] large meat packers dominated the livestock market by working cooperatively to jointly set prices and divide territories amongst themselves.[4] [5] In 1921, Congress enacted the Packers and Stockyards Act, 7 U.S.C. 181–229, to promote effective competition and integrity in livestock, meat, and poultry markets because it believed that the large packers employed anticompetitive or abusive practices that harmed producers and consumers.[6] The objective of the P&S Act is ''to assure fair trade practices in the livestock marketing . . . industry in order to safeguard farmers and ranchers against receiving less than the true market value of their livestock.'' [7] After the enactment of the P&S Act, several decades of relatively more competitive conditions in the livestock markets prevailed; however, structural shifts in the industry defined by technological and productivity advances and mergers and acquisitions by meat processors led to fewer and larger meat processors—increased market concentration—in the latter half of the 20th century. This transformation led to much larger sized packing plants, multi-plant packers and live poultry dealers; raised barriers to entry; reduced the number of meat processor competitors; and reduced competition. Today, greater use of bilateral and vertical contracting in the livestock and poultry industries also gives regulated entities greater practical ability to cause these harms in ways that are hard for producers to avoid.

The following table shows the level of concentration in the livestock and poultry slaughtering industries for 1980–2020 using four-firm Concentration Ratios (CR4).

[1] Parties may report tips or complaints to *farmerfairness.gov.* Additional information is available at *https://www.ams.usda.gov/services/enforcement/psd/reporting-violations.*

[2] 7 U.S.C. 181, including sections 203–205, 404, and 308 of the Act.

[3] Swift & Company, Armour and Company, The Cudahy Packing Company, Wilson & Co., Inc., and Morris & Company, Rosales, W.E., 2005. Dethroning economic kings: The Packers and Stockyards Act of 1921 and its modern awakening. *Journal of Agricultural & Food Industrial Organization, 3*(2). Accessed at *https://www.degruyter.com/document/doi/10.2202/1542-0485.1118/html* on 01–09–2024. *See also,* David Gordon, The Beef Trust: Antitrust Policy and the Meat Packing Industry, 1902–1922, at 230, 290 (1983) (Ph.D. Dissertation, Claremont Graduate School) (on file with the Wisconsin Historical Society Library) (referring to the ''Big Five'' and the ''Beef Trust'' interchangeably). *https://www.proquest.com/openview/b8fb565a39cdb1190b7b80e932cb8495/1?cbl=18750&diss=y&pq-origsite=gscholar&parentSessionId=XHRnq%2FulA9IQvIv3F8HNW40SbD8BIeNZTdBAIYAD8bQ%3D.*

[4] Rosales, William E. ''Dethroning Economic Kings: The Packers and Stockyards Act of 1921 and its Modern Awekening'' *Journal of Agricultural & Food Industrial Organization* 3, no. 2, access Feb. 1, 2024, (2005), *https://doi.org/10.2202/1542-0485.1118.*

[5] Christopher Leonard, ''The Meat Racket,'' (2015) and Witt, Howard. ''Hmong poultry farmers cry foul, sue'' Chicago Tribune. May 15, 2006. Available online at: *https://www.chicagotribune.com/news/ct-xpm-2006-05-15-0605150155-story.html.*

[6] The Packers and Stockyards Act: An Overview, National Agricultural Law Center, access Feb. 1, 2024, *https://nationalaglawcenter.org/overview/packers-and-stockyards/*

[7] *Bruhn's Freezer Meats* v. *U.S. Dep't of Agric.,* 438 F.2d 1332, 1337 (8th Cir. 1971), cited in *Van Wyk* v. *Bergland*, 570 F.2d 701, 704 (8th Cir. 1978) in AGRICULTURE DECISIONS Volume 72 Book One Part Two (P & S) Pages 371–434, page 13, access Feb. 1, 2024, *https://www.usda.gov/sites/default/files/documents/Vol%2072%20Book%201%20Part%202.pdf.*

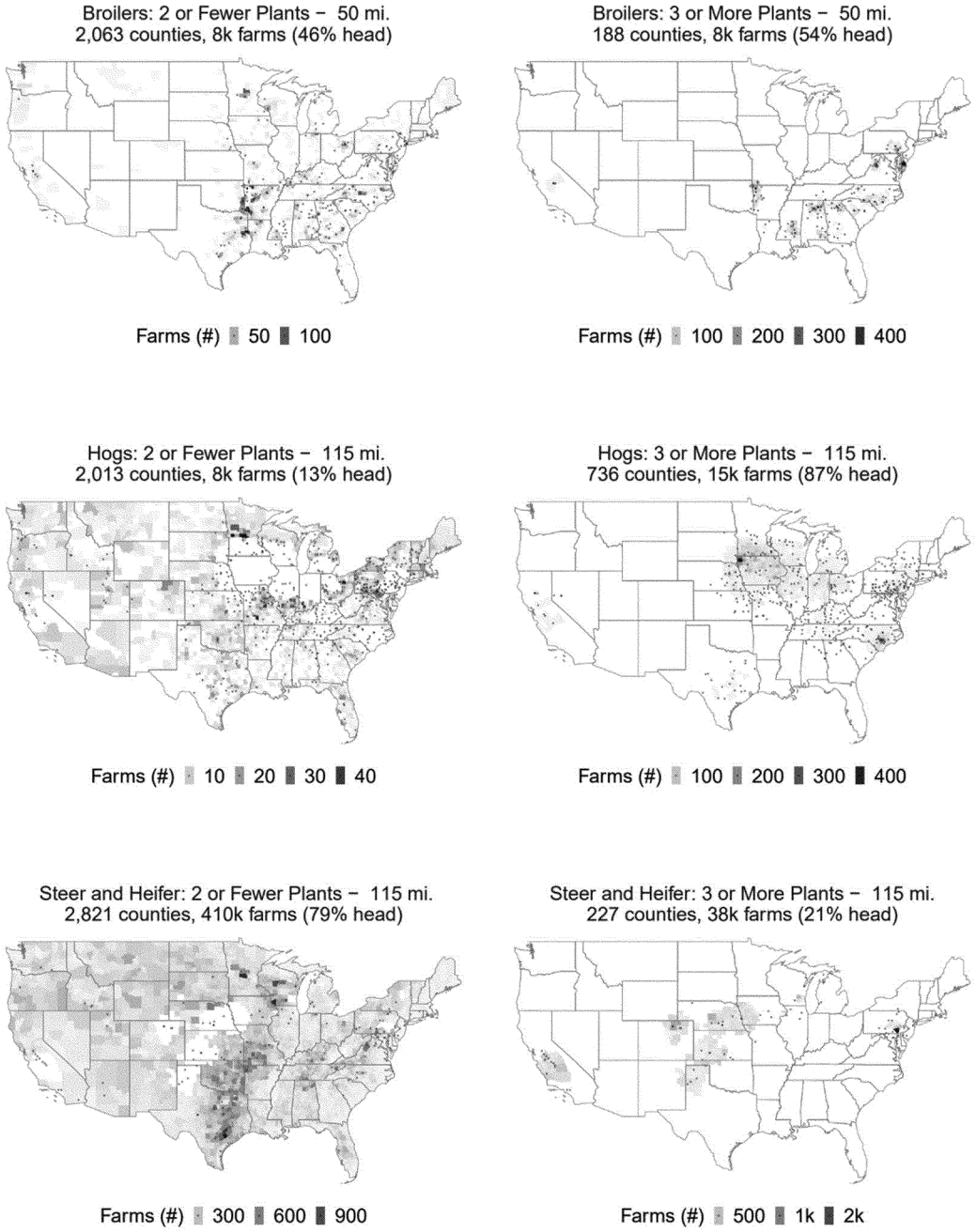
Table 1: Four-Firm Concentration Ratio in Livestock and Poultry Slaughter

Year	Steers & Heifers	Hogs	Broilers	Turkeys
	(%)	(%)	(%)	(%)
1980	36	34	32	40
1985	50	32	42	38
1990	72	40	41	45
1995	79	46	46	45
2000	82	57	49	41
2005	79	64	53	54
2010	85	65	51	56
2015	85	66	51	57
2020	81	64	53	55

Note: U.S. Department of Agriculture, AMS Packers and Stockyards annual reports. Available at https://www.ams.usda.gov/reports/psd-annual-reports.

The data are estimates of four-firm concentration ratios at the national level, but the relevant economic markets for livestock and poultry may be regional or local, where concentration may be higher than at the national level. The following figure shows the relative access that producers have to slaughter plants within various draw areas.

Figure 1. Relative Producer Access to Slaughtering Plants, 2017



Note: The figure shows the number of slaughter plants (2017): 2 or fewer (left) or 3 or more (right) within 50 miles (broiler - top) and 115 miles (hog – middle, steer and heifer – bottom) for broiler, hog, and cattle farms.[8]

[8] Meat, Poultry and Egg Product Inspection Directory by Establishment Name, by Number, and Demographic Data, USDA Food Safety Inspection Service, available at *https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory*. Big Meat Acquisition Datasets, Yale Thurman Arnold Project, access Feb. 1, 2024, (2021), *https://som.yale.edu/centers/thurman-arnold-project-at-yale/agriculture-and-antitrust*. Haines, Michael, Fishback, Price, and Rhode, Paul. United States Agriculture Data, 1840–2012, Inter-university Consortium for Political and Social Research [distributor], access Feb. 1, 2024, (2018), *https://doi.org/10.3886/ICPSR35206.v4* (County-level census data from 1978–2012). USDA Census of Agriculture Large Datasets, USDA National Agricultural Statistics Services, access at Feb. 1, 2024, *https://www.nass.usda.gov/datasets/* (Livestock data from 1997–2017). Ward, C.E., Meatpacking plant capacity and utilization: Implications for competition and pricing, access at Feb. 1, 2024, (1990), *https://doi.org/10.1002/1520-6297(199001)6:1%3C65::AID-AGR2720060107%3E3.0.CO;2-V* (Estimating travel distances for cattle to be around 100 miles). MacDonald, James M. & Ollinger, Michael & Nelson, Kenneth E. & Handy, Charles R., 2000, ''Consolidation In U.S. Meatpacking,'' Agricultural Economic Reports 34021, United States Department of Agriculture, Economic Research Service, access at Feb. 1, 2024, (2020), *https://www.ers.usda.gov/*

Continued

Half of all broiler growers have two or fewer processors for which they can grow broilers.[9] The following table is a modification of a table in MacDonald (2012),[10] adding the market concentration measure, the Herfindahl-Hirshman Index (HHI) [11] indices to MacDonald's calculations of the integrators, *i.e.,* live poultry dealers who typically have vertically integrated production, in the broiler grower's geographic region. The HHIs in the table assume equal market share for each integrator and, as such, are the minimum HHIs possible (at least with 2 to 4 growers). They show that 88.4 percent of growers are facing an integrator HHI of at least 2,500. The data suggest that most contract broiler growers in the U.S. are thus in markets where the live poultry dealers have the potential to exercise market power.

Table 2: Integrators in the Broiler Growers' Region and Associated Market Power Indices

Integrators in grower's area	Minimum HHI of integrators in grower's area	Farms (broiler operations)	Production (lbs. of broilers removed)	Can change to another integrator
Number	*HHI*	*Percent of total*		*Percent of farms*
1	10,000	21.7	24.5	7
2	5,000	30.2	31.7	52
3	3,333	20.4	19.7	62
4	2,500	16.1	14.8	71
>4		7.8	6.6	77

By the late 20th century and early 21st century, contracting practices were also changing. Bilateral and vertical contracting were becoming the increasingly dominant means to coordinate live animal supplies.[12] Today, most poultry production and about 98 percent of hog production fall under production contracts, and roughly 70 percent of cattle procurement falls under marketing contracts.[13] Bilateral and vertical contracting have benefits

webdocs/publications/41108/18011_aer785_1_.pdf?v=0. Smith, Timothy L., Andrew L. Goodkind, Tae-Gon Kim, Rylie E. O. Pelton, Kyo Suh, and Jennifer Schmitt, (2017). ''Subnational mobility and consumption-based environmental accounting of us corn in animal protein and ethanol supply chains'', Proceedings of the National Academy of Sciences (38), 114, access at Feb. 1, 2024, *https://doi.org/10.1073/pnas.1703793114* (Estimating travel distances for broilers to be 48 miles on average; and for pigs and cattle, ~115 miles). Beam, A.L. & Thilmany, Dawn & Pritchard, R.W. & Garber, L.P. & Metre, DC & Olea-Popelka, F.J.. (2015). Beam, A.L., D.D. Thilmany, R.W. Pritchard, L.P. Garber, DC Van Metre, and F.J. Olea-Popelka. ''Distance to Slaughter, Markets and Feed Sources Used by Small-Scale Food Animal Operations in the United States.'' Renewable Agriculture and Food Systems 31, no. 1, access at Feb. 1, 2024, (2016): 49–59. *https://doi.org/10.1017/S1742170514000441.* (Estimating transportation distances of 90 miles for 95 percent of percent of small-scale livestock operations). (Analysts filtered for plants that slaughtered beef, pork, and chicken. Analysts joined firm name appearing in directory to likely parent firm name by constructing a name lookup using merger data published by Yale Thurman Arnold Project; and manual internet search for poultry and livestock firms' mergers and acquisitions. Analysts obtained geographic coordinates from establishment address. For each establishment per animal class, analysts calculated the distance from the centroids of all U.S. counties to all plant establishments; and filtered for distances within 50 miles (broiler) and 115 miles (hog, cattle), based on estimates of travel distances for each animal obtained from literature search. Analysts calculated number of counties reachable by the travel distance for each animal species, *i.e.:* geographic draw area for each plant. Analysts produced for each county the number of plants appended with the parent firm name derived from the historic merger dataset described above. Analysts present as the summary figure the total number of unique parent firm names located within 90 (broilers) and 115 (hog, cattle) miles of county centroids that contain, for the purposes of this county-level analysis, the total number farm operations of each animal type in the county. Analysts summarized the number of counties, inventory, and operations with hog, broiler, and cattle sales, for all counties from 2017 NASS county-level dataset; and, for farm operations, filtered only for farm operations above the smallest class size, *e.g.:* for hog, above 25 head; for cattle, above 10 head; for broilers, above 2,000 head. This smallest class size is not likely to be utilizing the slaughter plants).

[9] MacDonald, J.M. and Key, N., 2012, Market power in poultry production contracting? Evidence from a farm survey, *Journal of Agricultural and Applied Economics, 44*(4), pp.477–490, access at Feb. 1, 2024, (2012), *https://www.proquest.com/scholarly-journals/market-power-poultry-production-contracting/docview/1183766436/se-2.*

[10] Ibid.

[11] The Herfindahl-Hirschman Index, HHI, is a ''commonly accepted measure of market concentration. The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers.'' U.S. Department of Justice, ''Herfindahl-Hirschman Index,'' accessed Feb. 1, 2024, (2018), *https://www.justice.gov/atr/herfindahl-hirschman-index.*

[12] *Lauck,* J. K. (1998). *Competition* in the *Grain Belt Meatpacking Sector After World* War. II. The annals of Iowa, 57(2), *https://pubs.lib.uiowa.edu/annals-of-iowa/article/id/10311/* (Finding that in 1984, only 7 percent of livestock were marketed through terminal markets. By this time, many packers made vertical contracts with farmers or feedlots). ''Structural Change in Livestock: Causes, Implications, Alternatives,'' Research Institute on Livestock Pricing 232728, Virginia Polytechnic Institute and State University, Department of Agricultural and Applied Economics, access at Feb. 1, 2024, (1990), available at *https://ideas.repec.org/p/ags/vtrilp/232728.html.* See James M. MacDonald and Christopher Burns, ''Marketing and Production Contracts Are Widely Used in U.S. Agriculture,'' Economic Research Service, (July 2019), available at *https://www.ers.usda.gov/amber-waves/2019/july/marketing-and-production-contracts-are-widely-used-in-us-agriculture/* (For a producer to successfully bring an animal to processing, they must secure a source of animals to raise, feed, medicine, and processing services, among other needs. In contract production, regulated entities typically control the inputs and processing and distribution channels, and therefore can largely block market access for independent producers seeking to bypass these tightly controlled, vertically contracted supply chains).

[13] USDA ERS, J. M. MacDonald and C. Burnes, (July 1, 2019), Marketing and Production Contracts Are Widely Use in U.S. Agriculture, *Amber Waves.* (In 2017, 49 percent of the value of livestock production was raised under contract agreements—usually between farmers and processors. Most poultry is produced under contract, and what is not produced under contracts between processors and growers is raised in facilities operated directly by processors. See graph for data on hogs.) *https://ers.usda.gov/amber-waves/2019/july/marketing-and-production-contracts-are-widely-used-in-us-agriculture/;* See also, USDA Packers and Stockyards Division (PSD), (2020), Packers and Stockyards Division Annual Report 2020, access at Feb. 1, 2024, *https://www.ams.usda.gov/sites/default/files/media/PackersandStockyardsAnnualReport2020.pdf.*

and disadvantages for both processors and producers. However, the exercise of market power through the contracting practices occurring in concentrated livestock and poultry markets have left producers susceptible to the conduct this rule aims to prohibit.

One of the notable structural changes over the course of the 20th century was the improvement in refrigeration technology. Refrigeration enabled meat packers to move away from the from Great Lakes and the Upper Midwest, where they could source large quantities of ice and build facilities closer to the centers of livestock production.[14] Slaughterhouse and fabrication plants, therefore, could and did move away from urban areas to remote rural locations. As technology and the ability to scale operations also grew in the latter half of the 20th century, plants also grew in size.[15]

These changes had two implications over time. First, as processing plants moved from urban to rural areas, producers were more vulnerable to an exercise of monopsony power because the local and regional markets became more concentrated.[16] Second, instead of terminal (auction) stockyards aggregating livestock for sales to packers, packers and producers increasingly entered into bilateral contractual relationships to buy livestock.[17] When producers utilized stockyards for their livestock sales, they could rely for protection on the provisions of title III under the Act, which established robust nondiscrimination protections for producers (in sec. 312), as well as a DOJ Consent Decree in 1920 with the major packers, which established that the stockyards had to be structurally separate from packers.[18] For example, in 1968 USDA issued a Statement of General Policy under the Packers and Stockyards Act to clarify that the prohibitions against unjust discrimination under sec. 312 governing ''just and reasonable stockyard services'' prohibited discrimination on the basis of race, religion, color, or national origin. However, as the industry structure evolved and livestock were increasingly sold through bilateral, vertical contracts, producers were no longer protected by sec. 312 of the Act. Instead, the sales were governed by title II of the Act, under which sec. 202(a) and (b) prohibits unjust discrimination and undue prejudice.[19] This final rule seeks to articulate the necessary protections around unjust discrimination and deception under those provisions of the Act.

The broiler industry also grew quickly after the Second World War. Early on it adopted a production model in which live poultry dealers contracted with poultry growers to grow-out broilers, rather than a model of independent producers selling broilers on the open market. With most broiler growing contracts, the live poultry dealer provides the chicks, the feed, and veterinary services, while the grower provides labor, facilities, equipment, and energy necessary to turn the chicks into slaughter-ready birds. At first, live poultry dealers were often feed suppliers, but now most processors act as live poultry dealers. Overall, the reality is that live poultry dealers have extensive control over production through the contracting practices.

Furthermore, it is important to acknowledge the impact of a consolidating farm production landscape overall. With the livestock and poultry farming sectors consolidating over the last several decades, the aggregate number of producers has declined significantly, even as total production is stable or growing. Many factors driving the loss of producers in the marketplace are the same factors underlying the market changes referenced above and include productivity growth wrought by scientific and technological advances, economies of scale, and transportation improvements. As shown in Figures 2 and 3 below, over the last 60 years, changes in animal production have corresponded to declines on the order of

[14] David I. Smith, (Spring 2019), 19th Century Development of Refrigeration in The American Meat Packing Industry, access at Feb. 1, 2024, *https://scholarworks.harding.edu/cgi/viewcontent.cgi?article=1118&context=tenor.* (''Development of refrigeration and transportation in Chicago led the city to become the meat packing center of the world,'' p. 100 from Howard Copeland Hill, ''The Development of Chicago as a Center of the Meat Packing Industry,'' Mississippi Valley Historical Review 10, no. 3 (1923): 253). (And, ''Refrigerator cars ''enabled dressed beef to be slaughtered in Chicago and shipped to the East at a lower cost than livestock,'' p. 103, from Mary Yeager Kujovich, ''The Refrigerator Car and the Growth of the American Dressed Beef Industry,'' The Business History Review 44, no. 4 (1970): 460.); Warren, Wilson, (2009), Tied to the Great Packing Machine: The Midwest and Meatpacking, Bibliovault OAI Repository, the University of Chicago Press, access at Feb. 1, 2024, *https://books.google.com/books?hl=en&lr=&id=f-CAclXhhCYC&oi=fnd&pg=PR7&dq=history+of+meat+packing&ots=oFnnxzABzR&sig=gp3eackbDY2CzAdcz8Q67cg0pvQ#v=onepage&q=history%20of%20meat%20packing&f=false* (Wilson notes that in the late 19th century plants were starting to move closer to livestock; and, by the 1950s, the industry hit the end of its third phase (1920s to 1950s) of packers buying direct from feedlots/producers and the decline of terminal markets.).

[15] MacDonald, J.M., Ollinger, M., Nelson, K.E. and Handy, C.R., (2000), Consolidation in US meatpacking. Economic Research Service, U.S. Department of Agriculture. Agricultural Economic Report No. 785, access at Feb. 1, 2024, *https://www.ers.usda.gov/webdocs/publications/41108/18011_aer785_1_.pdf?v=0#:~:text=Consolidation%20in%20slaughter%20features%20three,the%20location%20of%20animal%20feeders.*

[16] Willard Williams, ''Small Business Problems in the Marketing of Meat and Other Commodities (Part 4, Changing Structure of Beef Packing Industry),'' Hearings before the Subcommittee on SBA and SBIC Authority and General Small Business Problems of the Committee on Small Business, House, 96th Cong., 1st sess. (Washington, DC, 1979), 3; ''Structural Change in Livestock: Causes, Implications, Alternatives,'' Research Institute on Livestock Pricing 232728, Virginia Polytechnic Institute and State University, Department of Agricultural and Applied Economics, access at Feb. 1, 2024, (1990), available at *https://ideas.repec.org/p/ags/vtrilp/232728.html;* Lauck, J. K., (1998), Competition in the Grain Belt Meatpacking Sector After World War. II. The annals of Iowa, 57(2), access at Feb. 1, 2024, available at *https://pubs.lib.uiowa.edu/annals-of-iowa/article/id/10311/;* Marion, Bruce W., ''Restructuring of Meat Packing Industries: Implications for Farmers and Consumers,'' Working Papers 204107, University of Wisconsin-Madison, Department of Agricultural and Applied Economics, Food System Research Group (1988), available at *https://ideas.repec.org/p/ags/uwfswp/204107.html;* Aduddell, Robert M. & Cain, Louis P., ''The Consent Decree in the Meatpacking Industry, 1920–1956,'' Business History Review, Cambridge University Press, vol. 55(3) 1981; Aduddell, Robert M., and Louis P. Cain. ''A Strange Sense of Deja Vu: The Packers and the Feds, 1915–82.'' Business and Economic History 11 (1982): 49–60. *http://www.jstor.org/stable/23702755* (Documenting the historic shift from terminal auctions, in which around 90 percent of livestock were marketed in the 1920s; to 75 percent in the 1940s; to just 7 percent by 1984 (Lauck 1998; Aduddell 1981). In terminal auctions, market participants, including producers, new independent packers, and retailers enjoyed the benefits of transparent pricing and many possible marketing channels. The number of terminal auctions doubled every decade from 1935–1955 (Aduddell 1981). In the latter half of the 20th century, a new generation of large packers located closer to producers; and built new facilities to process larger numbers of animals which they purchased directly from increasingly larger feedlots (Williams 1978). Various researchers during the time period documented how direct purchases from these packers accounted for a larger share of the industry's sales; and contributed to decreasing numbers of market transactions and bids in terminal markets. For example, for cattle, the number of single bid transactions for cattle increased by 64 percent from 1982 to 1987; and by 38 percent for hogs (Purcell 1990). In turn, producers facing fewer buyers often reported lower prices paid (Marion 1988).

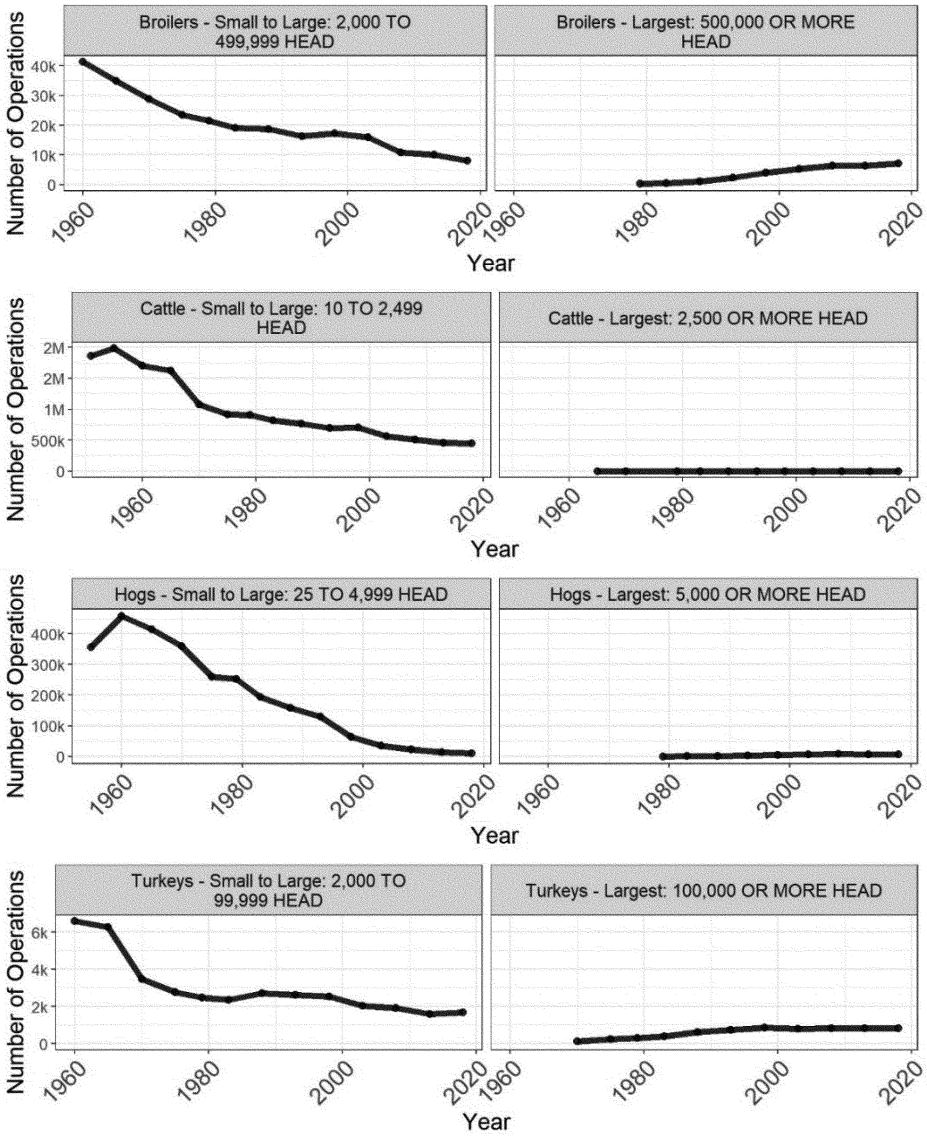
[17] Lauck, J.K., (1998), *Competition* in the *Grain Belt Meatpacking Sector After World* War. II. The annals of Iowa, 57(2), access Feb. 1, 2024, available at *https://pubs.lib.uiowa.edu/annals-of-iowa/article/id/10311/;* Unknown (W. Purcell, editor), (1990), ''Structural Change in Livestock: Causes, Implications, Alternatives,'' *https://ideas.repec.org/p/ags/vtrilp/232728.html.* Research Institute on Livestock Pricing Virginia Polytechnic Institute and State University, Department of Agricultural and Applied Economics, available at *https://ideas.repec.org/p/ags/vtrilp/232728.html;* Dickes, L.A. and Dickes, A.L. (2002), ''Oligopolists then and now: a study of the meatpacking industry,'' In *Allied Academies International Conference. Academy for Economics and Economic Education. Proceedings* (Vol. 5, No. 1, p. 15). Jordan Whitney Enterprises, Inc. *https://www.proquest.com/openview/919b243381c017244c764591d3d50a90/1?pq-origsite=gscholar&cbl=38640.*

[18] Aduddell 1981, *supra.*

[19] 7 U.S.C. 192(a) and (b).

hundreds of thousands of producers in nearly every size class except the largest, which increased by only hundreds of producers.[20]

Figure 2: Declines in Number of Small to Large Poultry and Livestock Operations While Numbers of the Largest Size Increased

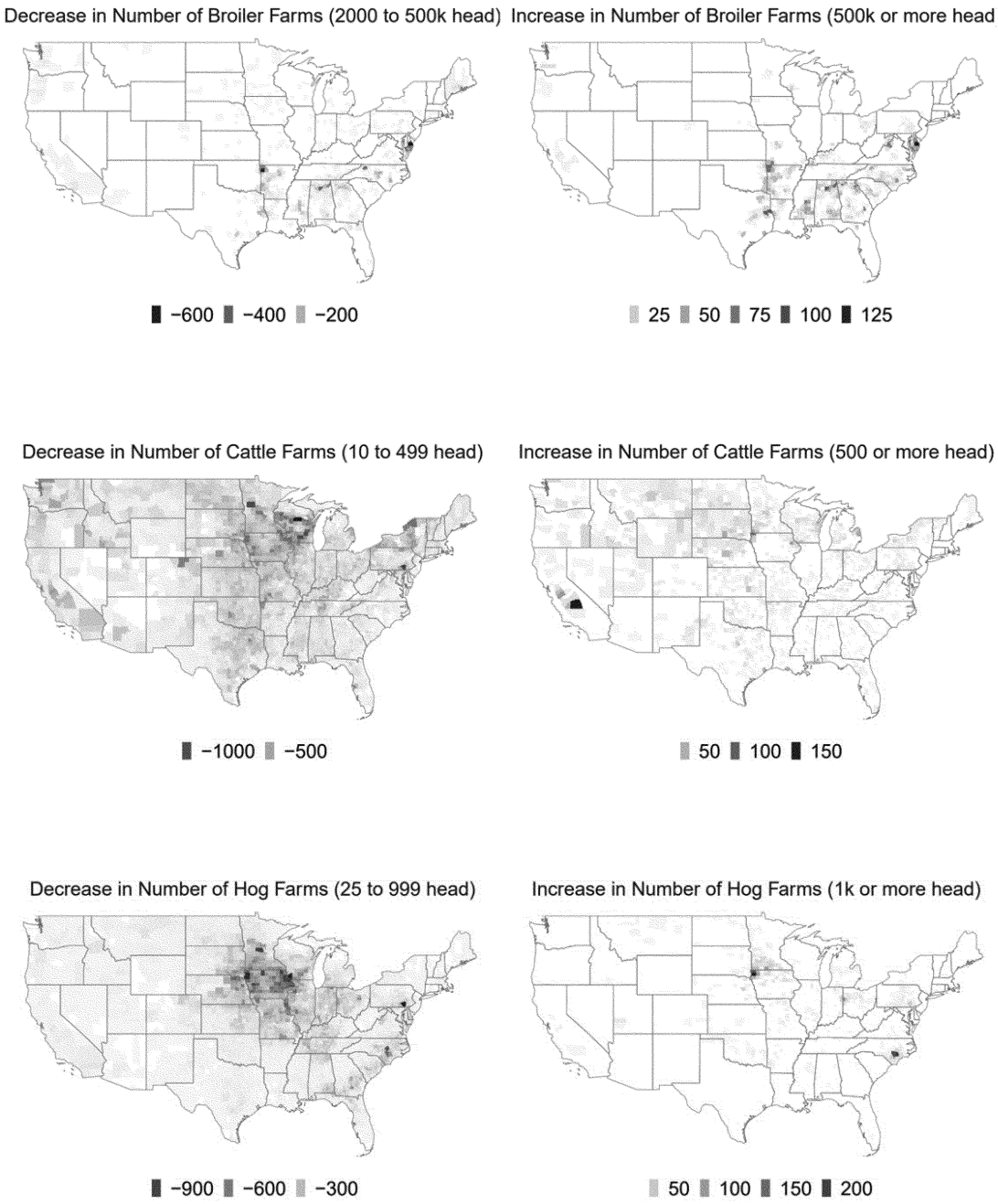


Note: The number of producers annually producing 2,000 to 499,999 boilers (top), 10 to 2,499 head of cattle (second row), 25 to 4,999 head of hogs (third row), and 2,000 to 99,999 head of turkeys (bottom row) in the U.S. decreased by thousands to hundreds of thousands of operations from 1978 to 2017 (left); while the number of operations of the largest size class (right) increased on a smaller order or remained stagnant.[21]

[20] Haines, Michael, Fishback, Price, and Rhode, Paul. United States Agriculture Data, 1840–2012, Inter-university Consortium for Political and Social Research [distributor], (2018), *https://doi.org/10.3886/ICPSR35206.v4* (County-level census data from 1978–2012). USDA Census of Agriculture Large Datasets, USDA National Agricultural Statistics Services, available at *https://www.nass.usda.gov/datasets/* (Livestock data from 1997–2017).

[21] USDA Census of Agriculture Historical Archive, USDA National Agricultural Statistics Services, available at *https://agcensus.library.cornell.edu/* (National-level statistics from 1978–2012); USDA Census of Agriculture 2017, USDA National Agricultural Statistics Services, available at *https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/* (National-level statistics for 2017) (Analysts obtained the total number of operations with sales for each animal size class from historic national-level statistics from 1978–2017. Analysts summed the number of operations of every class other than the largest size class for each animal species, compared to the largest size class; and excluded the very smallest size class in each summary because the smallest size is not likely to receive slaughter services by regulated entities).

Figure 3: Change in Number of Farm Operations: 1978 - 2017



Note: Decreases (left) in the number of farm operations from 2,000 to 500,000 broiler head produced annually (top), 10 to 499 cattle head (middle), and 25 to 999 hog head (bottom) coincided with increases in the number of the largest size class (right) for each animal operation from 1978 – 2017.

In the figure above, the intensity of shading indicates the magnitude of decrease (left) or increase (right), with shading intensity scaled individually to each map panel. Generally, the number of cattle and hog operations for every size class except the largest decreased in many counties across the U.S., while the number of operations for the largest size class increased in only a few counties. Owing to the limitations of available county-level data, the above map for cattle operations include both feedlot and cow-calf operations, of which only the first sell directly to packers in most instances. Feedlots and packers tended to locate closer to producers in the latter half of the 20th century. As feedlots became larger and more concentrated, the number of farms with fed cattle sales declined. For example, McBride found that from 1978–1992, as the distribution of cattle feedlots became geographically tighter, the number of counties contributing to half of cattle sales decreased from 73 counties in 1978 to just 44 counties in 1992, with a fourth

of sales coming from 13 counties. The number of feedlots declined from approximately 175,155 in 23 states in 1970 to 27,000 feedlots in 2020, with half of all fed cattle from just 132 of them.[22]

Data from Figure 3 clearly indicate a shift in livestock and poultry raising to larger farms. This shift has occurred in concert with an increase in bilateral and vertical contracting. Bilateral and vertical contracting facilitate the conditions in which discrimination and retaliation are more likely to restrict market opportunities of producers and cause them to earn less than the full value of their animals. It is harder to discriminate in the aggregated market of the stockyard than through bilateral contracting regimes. When producers are locked into long-term agreements with a single buyer, it is easier for buyers to discriminate on prohibited bases or retaliate in response to protected activities because they exercise considerably more leverage over producers. Buyer-seller relationships are more fixed, providing much less flexibility for producers. Furthermore, with the number of farms declining in number, the economic harms of discrimination and retaliation are more likely to be permanent as being denied a long-term contract may lead to permanent exclusion from the market. Smaller farms in particular may be more likely to be permanent casualties of discriminatory or retaliatory behavior in a consolidated farm context as buyers gravitate toward larger suppliers to more easily satisfy their volume requirements. Discriminatory or retaliatory behavior is more likely to harm producers economically because it is much harder to find alternative buyers in a world with fewer, bigger farms and fewer, bigger packers and live poultry dealers. This rule is not directly addressing consolidation at the farm level or concentration at the processor level, but in providing more protections to producers from discriminatory and retaliatory conduct, it is helping to prevent market exclusion.

A long-time scholar of these markets stated as early 2004 that the livestock and poultry markets appear to be by ''invitation only.'' [23] That statement underscores the power of incumbent entities to control access to the market and, in many ways, the destiny of what had been multigenerational successful operations of producers and smaller competitors.[24] This final rule addresses some of the ways that livestock and poultry markets unfairly exclude producers or otherwise limit their ability to obtain the full value of their animals. This final rule does not address all the factors contributing to market exclusion. However, it does address several practices that exclude producers and, in doing so, violate the Packers and Stockyards Act. AMS recognizes that creating inclusive and competitive markets with integrity requires multiple legal, regulatory, and programmatic strategies to mitigate the potential harmful effects of concentration and vertical contracting; build up alternatives through investments in regional meat and poultry processing; [25] and protect the rights of producers to develop producer organizations that advance farmer welfare, rural prosperity, and quality food. Thus, this rulemaking is one key piece to AMS's strong commitment to mitigating the factors that restrict market access for livestock and poultry producers.

B. Discrimination, Retaliation, and Deception

The P&S Act is a remedial statute enacted to address problems faced by farmers, producers, and other participants in the markets for livestock, meats, meat food products, livestock products in unmanufactured form, poultry, and live poultry; to protect the public from predatory practices; and to protect freedom for farmers and businesses to engage in the flow of commerce.[26] Thus, as academics and courts have noted, the Act has ''tort-like provisions that are concerned with unfair practices and discrimination'' that fulfill a ''market facilitating function,'' which Congress designed to prevent ''market abuse.'' [27] AMS interprets and implements the Act to achieve its core statutory purposes.[28]

AMS finds that current regulations under the Act do not sufficiently address the many unduly prejudicial, unjustly discriminatory, and deceptive practices in the livestock and poultry industry. As discussed above, the combination of increased concentration and use of vertical contracts in livestock and poultry markets enhances regulated entities' ability to unjustly discriminate against or deceive market participants and effect significant harm upon

[22] MacDonald, J.M., Dong, X., & Fuglie, K. (2023), Concentration and competition in U.S. agribusiness (Report No. EIB–256), U.S. Department of Agriculture, Economic Research Service, available at *https://doi.org/10.32747/2023.8054022.ers.* McBride, William D. (1997). ''Change in U.S. Livestock Production, 1969–92,'' Agricultural Economic Reports 262047, United States Department of Agriculture, Economic Research Service, available at *https://www.ers.usda.gov/webdocs/publications/40794/32767_aer754fm.pdf?v=1657.7.* ''Final Estimates for 1970–1975,'' USDA (1978), available at *https://downloads.usda.library.cornell.edu/usda-esmis/files/sq87bt648/7w62fc32q/qf85nf445/cattleest_Cattle_-_Final_Estimates__1970-75.pdf.*

[23] C. Robert Taylor, ''The Many Faces of Corporate Power in the Food System.'' Presented at DOJ/FTC Workshop on Merger Enforcement, February 2004, available at *https://www.justice.gov/sites/default/files/atr/legacy/2007/08/30/202608.pdf.*

[24] See, *e.g.,* Jon Lauck, ''Toward an Agrarian Antitrust: A New Direction for Agricultural Law,'' 75 N. D. L. Rev. 449 (1999); Peter C. Carstensen, ''Buyer Power and the Horizontal Merger Guidelines,'' 14 U. Penn. J. Bus. L. 775 (2012); Peter. C. Carstensen, ''Buyer Power, competition policy, and antitrust: the competitive effect of discrimination among suppliers,'' The Antitrust Bulletin: Vol. 53, No. 2/Summer 2008; Kenneth E. Boulding, ''Towards a Pure Theory of Threat Systems,'' The American Economic Review, May, 1963, Vol. 53, No. 2, 424–434.

[25] *https://www.usda.gov/media/press-releases/2023/04/19/usda-announces-funding-availability-expand-meat-and-poultry.*

[26] *Stafford* v. *Wallace,* 258 U.S. 495 (1922). *Bruhn's Freezer Meats of Chicago, Inc.* v. *U. S. Dep't of Agric.,* 438 F.2d 1332, 1337–38 (8th Cir. 1971) (quoting H.R. Rep. No. 1048, 85th Cong., 1st Sess. (1957), U.S. Code Cong. & Admin. News 1958, p. 5213). Public Law 99–198, 99 Stat. 1535, 7 U.S.C. 1631 (Section 1324 of the Food Security Act). Fed. Trade Comm'n, Report of the Fed. Trade Comm'n on the Meat-Packing Industry, Part I (Extent and Growth of Power of the Five Packers in Meat and Other Industries); Fed. Trade Comm'n, Report of the Fed. Trade Comm'n on the Meat-Packing Industry, Part II (Evidence of Combination among Packers); Fed. Trade Comm'n, Report of the Fed. Trade Comm'n on the Meat-Packing Industry, Part III (Methods of the Five Packers in Controlling the Meat-Packing Industry) (1919) (Finding that the purpose of the combination of Big Five packers was to ''monopolize and divide among the several interests the distribution of the food supply not only of the United States but of all countries which produce a food surplus, and, as a result of this monopolistic position, to extort excessive profits from the people not only of the United States but a large part of the world'').

[27] Herbert Hovenkamp, ''Does the Packers and Stockyards Act Require Antitrust Harm?'' (2011). Faculty Scholarship at Penn Carey Law. 1862. *https://scholarship.law.upenn.edu/faculty_scholarship/1862* (''subsections (a) and (b) appear to be tort-like provisions that are concerned with unfair practices and discrimination, but not with restraint of trade or monopoly as such''); Peter Carstensen, The Packers and Stockyards Act: A History of Failure to Date, CPI Antitrust Journal 2–7 (April 2010) (''Congress sought to ensure that the practices of buyers and sellers in livestock (and later poultry) markets were fair, reasonable, and transparent. This goal can best be described as market facilitating regulation.''); Michael C. Stumo & Douglas J. O'Brien, ''Antitrust Unfairness vs. Equitable Unfairness in Farmer/Meat Packer Relationships,'' 8 Drake J. Agric. L. 91 (2003); Michael Kades, ''Protecting livestock producers and chicken growers,'' Washington Center for Equitable Growth (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf* (''Section 202's prohibitions on unjust discrimination and undue preference are not limited to conduct that destroys or limits competition or creates a monopoly. These provisions address conduct that impedes a well-functioning market and deprives livestock and poultry producers of the true value of their animals. Taken together, these provisions seek to prevent market abuses.'').

[28] See *Bowman* v. *U.S. Dep't of Agric.,* 363 F.2d 81 at 85 (5th Cir. 1966).

producers. With bilateral contracts where one side has significant market power, regulated entities can target specific individuals, whether because of their personal characteristics (prejudice) or because of they have engaged in certain activities (retaliation). With market concentration, producers have limited options in the marketplace with which to avoid the harms. Vertical contracts where regulated entities have greater control over producers' operations also enable certain forms of discrimination, such as in the provision of inputs, as live poultry dealers particularly have heightened control and involvement in the growers' poultry operations. The provision of accurate and not misleading information also takes on heightened importance in these markets. In markets where producers are exiting, it is especially difficult for producers to reenter after being excluded, and the harms from exclusion are significant.

i. Discrimination and Prejudice

Discrimination and prejudice harm market participants and overall market integrity and efficiency. Discrimination is economically inefficient.[29] The prejudicing entity that pays a producer below market value for his or her cattle or hogs because the producer belongs to a protected class causes that producer to not receive the full economic value of his or her animals; this discrimination also prevents the market from reaching an optimal allocation of wages and labor, contributing to a deadweight loss for the economy at large.[30] Likewise, a regulated entity's refusal to buy from a producer of a protected class offering animals of comparable quality to those being sold by other producers to that same buyer in the same time-frame may cause that disfavored producer to exit the market.[31] If an entity refuses to purchase product from a producer of a particular class who offers identical product, such as cattle, that disfavored producer may face a lower price, resulting in a loss to the producer that may discourage the producer from continuing to operate or would-be producers of that class from entering the market.[32] Using non-economic characteristics of the livestock or poultry producers to dictate patterns of production thwarts efforts by producers to accurately assess market conditions and make sound business decisions.

In comments to the proposed rule, multiple organizations spoke of the widespread economic harms resulting from discrimination and prejudice in livestock and poultry markets.[33] A producer advocacy organization reported that ''discrimination, retaliation, and deception have become common features of livestock and poultry markets, leading to widespread fear and anxiety among producers.'' [34] Another commenter wrote, ''The current ability to exclude marginal competitors and exploit covered producers, rather than producing meaningful price discovery and transparency in the production and sales of livestock, meat and poultry, has greatly injured not only those involved in production but has restricted consumers from accessing reliable, affordable sources of protein.'' [35] We acknowledge that these comments addressed what commenters viewed as a range of discrimination that could be covered by the proposed rule, and some that we are not addressing in this rule. Comments relating to these topics are discussed further in Section V—Changes from the Proposed Rule, and in Section VII—Comment Analysis.

As previously noted, this rule does not address every form of discrimination or prejudicial exclusion or disadvantage in the marketplace but focuses on providing clarity regarding certain specific discriminatory and prejudicial practices that AMS has identified in this final rule as essentially unjust, which offer no benefits to the competitive market or producers, and which undermine competition on the merits of the products and services that producers offer. Additionally, although the descriptive analyses set forth below do not address the prevalence or degree or prejudice for each and every prohibited basis, owing to the limitations of available data, AMS believes that leaving out any of the bases listed in this rule would be inappropriate. Not only would that be inconsistent with the Department's approach toward discrimination in other contexts, as repeatedly endorsed by Congress, but the resulting uncertainty could also open the door to those forms of discrimination in livestock, poultry, and related markets under the Act, which would be contrary to the purposes of this regulation and

[29] Stiglitz, J. ''Approaches to the Economics of Discrimination,'' *American Economic Review,* vol. 63/2, May 1973: 287–295 (Discussing how discrimination in markets produces an economic inefficiency: ''If all firms are profit maximizers, then all will demand the services of the low-wage individual, bidding their wages up until the wage differential is eliminated. Why does this not occur?'').

[30] Ibid.

[31] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Livestock Industry Agenda, August 27, 2010, Fort Collins, Colorado, available at *https://www.justice.gov/media/1244701/dl?inline; https://youtu.be/Ygerhjjp0Is?si=2L7OQh0I87fc1n1I&t=1885* (Producers described how packers could ''pick . . . large entities'' as part of marketing agreements to procure supply. In turn, this drove up an excess supply and drove down prices for producers or suppliers who did not receive such an agreement in the cash-negotiated market. One producer said that this discrimination had the effect of ''controlling . . . inventory;'' another said that this conduct had the effect of ''tens of thousands of independent producers being purged out of the business or going into bankruptcy . . . exited out of agriculture'').

[32] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Livestock Industry Agenda, August 27, 2010, Fort Collins, Colorado, available at *https://www.justice.gov/media/1244701/dl?inline; https://youtu.be/Ygerhjjp0Is?si=2L7OQh0I87fc1n1I&t=1885* (Producers described how packers could ''pick . . . large entities'' as part of marketing agreements to procure supply. In turn, this drove up an excess supply and drove down prices for producers or suppliers who did not receive such an agreement in the cash-negotiated market. One producer said that this discrimination had the effect of ''controlling . . . inventory''; another said that this conduct had the effect of ''tens of thousands of independent producers being purged out of the business or going into bankruptcy . . . exited out of agriculture'').

[33] Government Accountability Project, Comments on Proposed Rule: Inclusive Competition and Market Integrity, (AugJan. 20232), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0427* (''Many of these Vietnamese growers were enticed to sell profitable businesses and family homes and take out huge loans to enter broiler production contracts. Bearing all the same burdens of other broiler producers, they were further victimized by language barriers, cultural differences, and blatant mockery and exploitative behavior. In some cases, to keep their contracts, Vietnamese growers were asked to do additional work that was not required of white counterparts. Many of the Vietnamese farmers we have spoken to have likened the abusive and threatening behavior of their integrators to the communist government from which they fled'').

Rural Advancement Foundation International—USA, Comments on Proposed Rule: Inclusive Competition and Market Integrity, (AugJan. 20232), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0437* (''They don't have to cut you off, they can just bleed you dry. The barn we're sitting in here hatched flocks with salmonella issues. They can send those compromised flocks to growers they want to bleed.'' ''My main concern is that [my integrator] operates on fear and threatening tactics to make every grower they have scared they are going to lose their contract every single day. No human being should have to live every single day in fear that their livelihood and only source of income can be taken away from them. I am sick of it, someone needs to do something to help us! I love to grow chickens and feed the world, but I do not like to live as if under a dictatorship.'' ''When I filed a complaint with the Packers and Stockyards Division about a weight issue, in which I was proven right, I was punished with bad tournament grouping for a year. Also, I have been told by my integrator, after receiving a really bad flock of birds, that they would be sure to not let it happen next time—so they know how to make it happen!'').

[34] Food & Water Watch, ''Comment on AMS–FTPP–21–0045: Inclusive Competition and Market Integrity Under the Packers and Stockyards Act,'' (Jan. 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0423.*

[35] Rocky Mountain Farmers Union, ''RMFU Comment for the Proposed Rule Inclusive Competition and Market Integrity Under the Packers and Stockyards Act'' (Jan. 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0441.*

the Act, which prohibits ''undue prejudice . . . in any respect.''

a. Discrimination and Prejudice on Personal Characteristics and Status

AMS (including its predecessor agencies) has received complaints over the years of discrimination against producers, in particular in the poultry industry, and especially on the basis of race. The Agency has not always been able to act on these complaints for a variety of reasons. The Agency also believes that some complaints may have been suppressed due to the risks of retaliation, which are discussed below. As highlighted below, comments to this rulemaking affirmed the prevalence and remaining challenge of discrimination on prohibited bases.

Researchers have documented the history of discrimination against racial and ethnic minorities in agricultural markets. Multiple factors have contributed to the decline of non-white-owned farms, specifically to the decline of Black-owned farms, including the Homestead Act of 1862, the Morrill Land Grant Act of 1862, lack of legal protections for heirs' property, and limited access to capital through discriminatory lending practices.[36] For example, in the earlier part of the 20th century, the Federal government and agricultural landholders restricted land sales, engaged in predatory and fraudulent lending practices, and denied farm support programs to Black farmers and ranchers,[37] which has resulted in the loss of Black economic security and land loss.[38] [39] [40] [41] A 1959 paper reported ''significant market discrimination'' against Black American producers in the Southern United States.[42] Discrimination by the Federal government and private sector also caused Hispanic people and American Indian people farming on reservations to lose farmland and decline in number.[43] [44] More recently, some news reports have documented that companies may present contract terms to non-native English speaking immigrant communities who may not understand them, and have spotlighted the treatment of Asian American and Pacific Islander poultry growers in particular.[45]

Researchers have also documented some of the adverse outcomes, including economic outcomes, caused by discrimination. In the livestock sector, the results of historical prejudice and the risk of present-day prejudice are apparent when looking at data from the 2017 Census of Agriculture, which show that a small fraction of livestock farms with production contracts are operated by Black, Asian, American Indian, or Native Hawaiian producers (Figure 1).[46] In Figure 1, the checkered bars represent the share of racial and ethnic groups among all livestock and poultry farms, and the colored bars indicate the share of production contracts received by each group. As indicated in Figure 1, American Indian, Black, Native Hawaiian, and Hispanic producers receive less than a proportional share of livestock and poultry production contracts relative to their respective populations. For example, Black producers and growers account for 1.6 percent of U.S. farms by race and ethnicity and receive a disproportionately lower 0.5 percent of livestock and poultry contracts. White producers and growers, meanwhile, represent 91 percent of all farms, but 98 percent of hog contracts and 97 percent of cattle contracts—a greater than proportionate share of livestock contracts, and at 90 percent, a lower than proportionate share of poultry contracts. Non-white racial and ethnic groups constitute a very small share of contracted livestock and poultry producers, which can be attributed to limited access to land and capital,[47] having on average smaller operations, and discrimination.

[36] McKinsey & Company. November 10, 2021. Black Farmers in the U.S: The Opportunity for Addressing Racial Disparities in Farming. Accessed at Black farmers in the US: The opportunity for addressing racial disparities in farming | McKinsey on 10/04/2023; and *https:/www.archives./gov/milestone-documents/morrill-act https://www.archives.gov/milestone-documents/morrill-act* (see, *e.g.,* ''People of color were often excluded from these educational opportunities due to their race.'').

[37] Francis, Dania V., Darrick Hamilton, Thomas W. Mitchell, Nathan A. Rosenberg, and Bryce Wilson Stucki. ''Black Land Loss: 1920–1997.'' In AEA Papers and Proceedings, vol. 112, pp. 38–42. American Economic Association, 2022.

[38] U.S. Department of Agriculture, National Agricultural Library, ''Heirs' Property,'' *https://www.nal.usda.gov/farms-and-agricultural-production-systems/heirs-property* (last accessed Aug. 2022).

[39] Mitchell, Thomas W. 2019. Historic Partition Law Reform: A Game Changer for Heirs' Property Owners. In Heirs' property and land fractionation: fostering stable ownership to prevent land loss and abandonment. *https://www.fs.usda.gov/treesearch/pubs/58543* (last accessed 8/9/2022).

[40] U.S. Commission on Civil Rights. 1965. Equal Opportunity in Farm Programs: An Appraisal of Services Rendered by Agencies of the U.S. Department of Agriculture. *https://files.eric.ed.gov/fulltext/ED068206.pdf* US Commission on Civil Rights. 1982. ''The Decline of Black Farming in America.'' *https://eric.ed.gov/?id=ED222604.*

[41] Feder, J. and T. Cowan. 2013. ''*Garcia* v. *Vilsack:* A Policy and Legal Analysis of a USDA Discrimination Case,'' Congressional Research Service report number 7–5700, February 22, 2013.

[42] Tang, Anthony M. ''Economic development and changing consequences of race discrimination in Southern agriculture.'' *Journal of Farm Economics* 41, no. 5 (1959): 1113–1126.

[43] Casey, Alyssa R. Racial Equity in U.S. Farming: Background in Brief 2021. Congressional Research Service. *https://crsreports.congress.gov/product/pdf/R/R46969* (Finding that the percent of American Indian and Hispanic producers increased by 1.3 and 2.4 percent between the early 1900s to 2017, compared to White producers which increased by 9 percent).

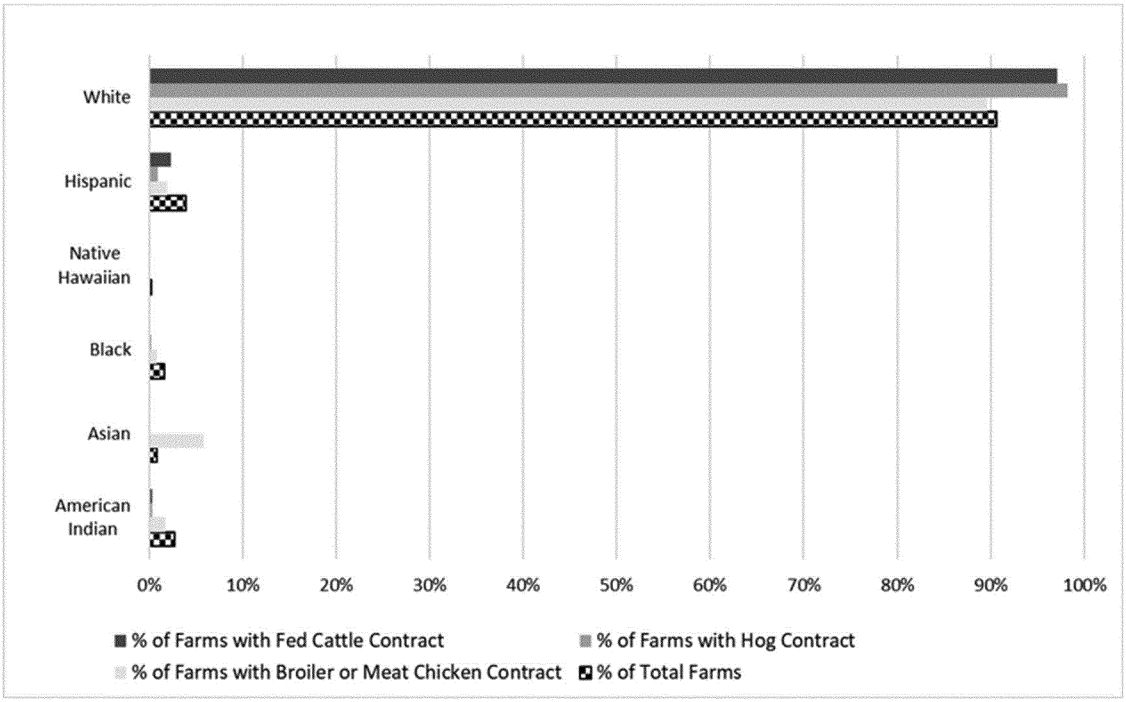
[44] Horst, M., Marion, A. ''Racial, ethnic and gender inequities in farmland ownership and farming in the U.S.'' *Agric Hum Values* 36, 1–16 (2019), available at *https://doi.org/10.1007/s10460-018-9883-3.*

[45] Christopher Leonard, ''The Meat Racket,'' (2015) and Witt, Howard. ''Hmong poultry farmers cry foul, sue'' Chicago Tribune. May 15, 2006. Available online at: *https://www.chicagotribune.com/news/ct-xpm-2006-05-15-0605150155-story.html.*

[46] Most production contracts are held by poultry growers and less so by packers. A production contract, according to USDA NASS, ''is an agreement between a producer or grower and a contractor (integrator) setting terms, conditions, and fees to be paid by the contractor to the operation for the production of crops, livestock, or poultry.'' In contrast, many packers hold marketing contracts which, according to NASS, are ''based strictly on price.'' USDA NASS, No Date. ''Appendix B. General Explanation and Census of Agriculture Report Form.'' usappxb.pdf (*usda.gov*), accessed 8/12/23.

[47] See, generally, Congressional Research Service, ''Racial Equity in Farming,'' Nov. 2021, available at *https://crsreports.congress.gov/product/pdf/R/R46969;* Economic Research Service, USDA, ''Access to Farmland by Beginning and Socially Disadvantaged Farmers: Issues and Opportunities,'' Dec. 2022, available at *https://www.ers.usda.gov/publications/pub-details/?pubid=105395.*

Figure 4. Percent of Farms Owned by Race and Ethnicity Compared to Percent of Farms that Received Livestock and Poultry Contracts



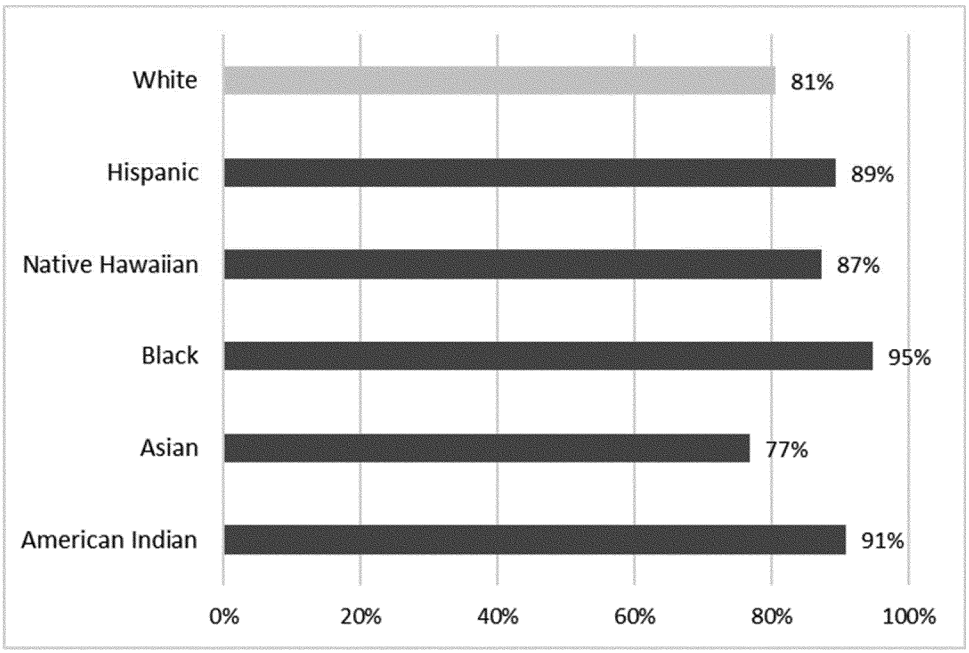
Data source: 2017 Agricultural Census, National Agricultural Statistical Service, USDA.

Disparities are also found in income across racial and ethnic groups. It is difficult to disentangle historical discrimination—whether that be prejudicial administration of USDA farm policies, racial segregation laws, or discriminatory private lending policies, from current discrimination practiced by livestock and poultry companies. Figure 5 shows the percentage of livestock and poultry farms (omitting nonfamily farms) by the reported race or ethnicity, and categorized by the lowest level of Gross Cash Farm Income (GCFI), which is annual income before expenses, including cash receipts, farm-related cash income, and government payments.[48] These data indicate that livestock and poultry farms with producers who identify as American Indian, Black, Native Hawaiian, and Hispanic are more likely to be in the lowest income category (measured by GCFI <$150,999) than their white counterparts. Those farms with producers who identify as Asian are less likely than their White counterparts to fall into the lowest income group, which might be a factor of being relatively recent immigrants and not facing past discrimination.[49] The fact that Black, Native Hawaiian, Native American, and Hispanic livestock and poultry farmers are more likely to be in the lower income GFCI category could be an effect of past discrimination, and it also could make such producers more vulnerable to current discriminatory behavior by packers. Markets dominated by one or a few large packers or live poultry dealers may also be less accessible to these lower income farms, which have limited financial or other economic resources with which to engage.

[48] USDA ERS, No date. Farming and Farm Income. Available at *https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/farming-and-farm-income/* (last accessed 9/8/23). GCFI income categories incude <$149,900, $150,000–$349,999, $350,000–$999,999, and ≥$1,000,000.

[49] Pew Research Center. June 19, 2012. The Rise of Asian Americans. Accessed at *https://www.pewresearch.org/social-trends/2012/06/19/the-rise-of-asian-americans/* on 10–13–23.

Figure 5. Percentage of Livestock and Poultry Family Farms by the Lowest GCFI Category (< $150,000), Race, and Ethnicity



Data source: 2017 Agricultural Census, National Agricultural Statistical Service, USDA.

Recent research conducted by the USDA's Office of the Chief Economist and presented at the Agricultural & Applied Economics Association [50] suggests that certain ethnic or racial groups are receiving lower prices compared to White producers from regulated entities in livestock and poultry contracts. In some cases, the research showed statistically significant differences in prices received for livestock (cattle and hogs) and broiler products across ethnic or racial groups after controlling for variables such as farm size, region, type of marketing contract or channel, organic certification status, distance to closest packer, and size of closest packer. Specifically, Black and American Indian cattle producers, Black contract broiler producers, and Black and American Indian hog producers all received lower prices for their livestock products relative to White producers. However, the effect of many animal quality variables, such as weight per animal, dressing percentage, and yield grade, cannot be controlled for under this analysis because the data is not in the Census of Agriculture or other data sets organized by race and ethnicity. Thus, endowment differences, such as better land and more capital, that represent the legacy of historical discrimination may account for a portion of these price differentials.

Differences in livestock and broiler prices could also be due, at least in part, to discrimination. Due to current data deficiencies, however, it is impossible to tell whether differences in prices received across ethnic or racial groups are due to current discriminatory practices, historic discrimination, or some combination thereof. These omitted variables may be correlated with race or ethnicity, and thus may account for a substantial portion of the price differentials. Additional data collection efforts may shed light on the role of omitted variables, such as animal size, thus helping to distinguish economic effects arising from current racial discrimination from disparate economic outcomes due to historical discrimination.

Gender is also a basis of discrimination in livestock and poultry markets. According to the 2017 Census, livestock and poultry operations where principal operators are female received significantly lower market value for the livestock and poultry they sell. Female principal operators in livestock and poultry earned 53 cents per operation for every dollar earned by male principal operators per operation. By comparison, in the broader U.S. population, females earn 77 to 82 cents for every dollar earned by men in 2022.[51] Figure 6 shows that the difference in livestock and poultry sales by gender is about $117,000 less per operation for female principal operators, or 47 percent less, compared to male principal-operated farms. Disproportionately more female operators are found in the lower income classes relative to males, and a disproportionately higher number of male operators are found in the highest income classes. The value of livestock and poultry production per total acres owned by males and females is $0.22 per acre for males and $0.18 per acre for females, or $0.82 per acre for female operators relative to every $1 per acre earned by male operators. Together, these data suggest that female

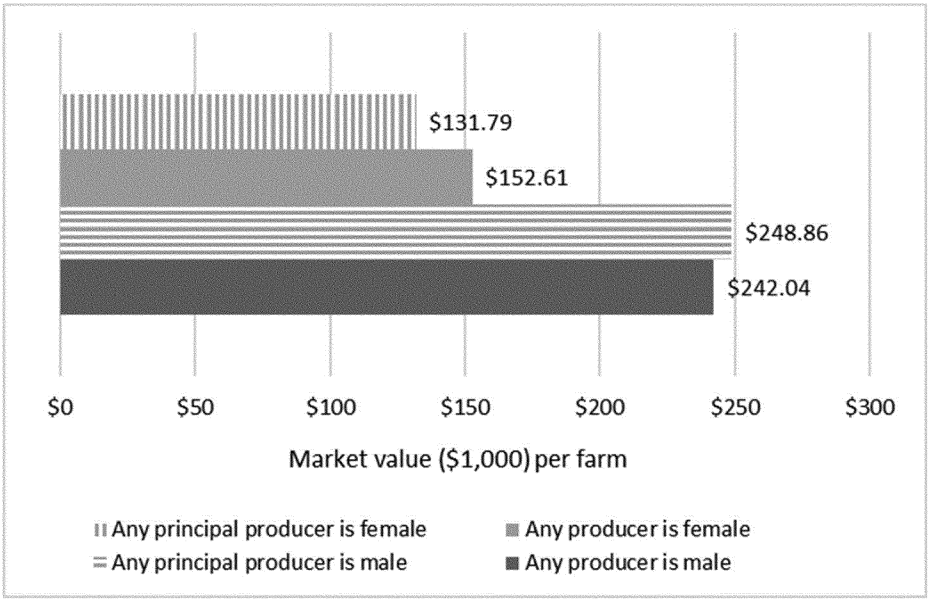
[50] Breneman, V., Cooper, J. Nemec Boeme, R. and Kohl, M., ''Competition and Discrimination—is there is a relationship between livestock prices received and whether the grower is in a historically underserved group?'' 2023 AAEA Annual Meeting, Washington, DC, July 23–July 25.

[51] The Pew Research Center. March 1, 2023. ''The Enduring Grip of the Gender Pay Gap.'' Accessed at *https://www.pewresearch.org/social-trends/2023/03/01/the-enduring-grip-of-the-gender-pay-gap/* on 09–25–2023, and World Economic Forum. July 2023. Global Gender Gap Report 2023 Accessed at WEF_GGGR_2023.pdf (*weforum.org*) on 09–225–2023.

producers—in livestock and poultry markets—achieve poorer economic outcomes than male producers.

markets—achieve poorer economic outcomes than male producers.

Figure 6. Market Value of Livestock, Poultry, and Their Products Per Farm by Gender



Data source: 2017 Agricultural Census, National Agricultural Statistical Service, USDA.

AMS also utilized a regression analysis showing support for disparities in income across different protected classes. Table 3 presents the empirical results of multivariate regression analysis of the 2017 Agricultural Census and other data by the USDA Office of the Chief Economist. Black and American Indian cattle and broiler producers, and Black and American Indian hog producers of owned hogs (hogs not sold under production contracts) all received lower prices for their livestock products relative to White producers. For example, Black and American Indian producers received around 5 percent lower broiler prices but no statistically significant decrease in payments for hogs delivered under production contracts. However, the effect of many animal quality variables, such as weight per animal, dressing percentage, and yield grade, cannot be controlled for under this analysis because the data is not in the Census of Agriculture or other data sets organized by race and ethnicity. Thus, endowment differences, such as better land and more capital, that represent the legacy of historical discrimination may account for a portion of these price differentials. Hawaiian contract hog producers received 68 percent higher prices even though producer location was controlled for in the analysis, but the analysis cannot control for some unknown factors associated with this relatively small cohort of producers that may account for this relatively large price effect.

Table 3: Impact of Personal Characteristics on the Price Received per Animal Delivered

Race, ethnicity, or gender of operators	Impact of race, ethnicity, or gender on price received per animal delivered			
	Broilers	All Hogs	Contract Hogs Only	Cattle
Black	-4.73%	-7.21%	0.00%	-2.53%
American Indian	-5.49%	-8.63%	0.00%	-4.08%
Hawaiian	0.00%*	0.00%	67.68%	0.00%
Asian	0.00%	0.00%	0.00%	0.00%
Female	0.00%	2.83%	0.00%	0.00%
Spanish Origin	0.00%	0.00%	0.00%	-2.55%
	Impact on price received with respect to age or experience			
Age**	-0.12%	-0.05%	N/A***	0.01%
Experience****	N/A	N/A	-0.24%	N/A

Source: 2017 Agricultural Census, National Agricultural Statistics Service, USDA

Notes: These results drawn from multivariate regression analysis assume all respondents (up to four) to the 2017 Agricultural Census survey have the personal characteristic in the row of the table. The Agricultural Census does not include information the size of the animals delivered or other quality characteristics. Hence, if these omitted variables are correlated with the personal characteristics of the producers, they can account for the impact of race/ethnicity/gender on prices. As such, it is impossible to separately identify price impacts of current ongoing racism from impacts associated with historic racism (e.g., price differences due smaller animals on account of lower financial endowments).

*If the underlying coefficient estimate used to make this estimate is of less than 10 percent statistical significance, the result in the table is set equal to zero.

**Average age of the individuals who were involved in the decisions of the farm operations and who responded to the Agricultural Census Survey.

***Average years of experience of the individuals who were involved in the decisions of the farm operations and who responded to the Agricultural Census Survey.

****N/A means the data is not available.

The results of an analysis presented in Table 3 found there is a statistically significant and positive relationship between female operators and price received for the owned-hog market, which includes producers of both contracted and owned hogs (the regression accounted for whether the producer was on a production contract or not through an explanatory variable), but which examines the price impact only on owned-hogs sold.[52] However, for the production contract-only hog market, which makes up about 70 percent of all hogs produced, this relationship becomes negative, though not at a statistically significant level (non-statistically significant results are shown as zero values in the table). From regression results not shown in Table 3, it appears that female contract hog producers who also produce owned hogs receive a higher price for owned hogs than female farmers who only produce owned hogs. This finding suggests that females with hog contracts face preferential prices relative to those females that do not hold contracts.

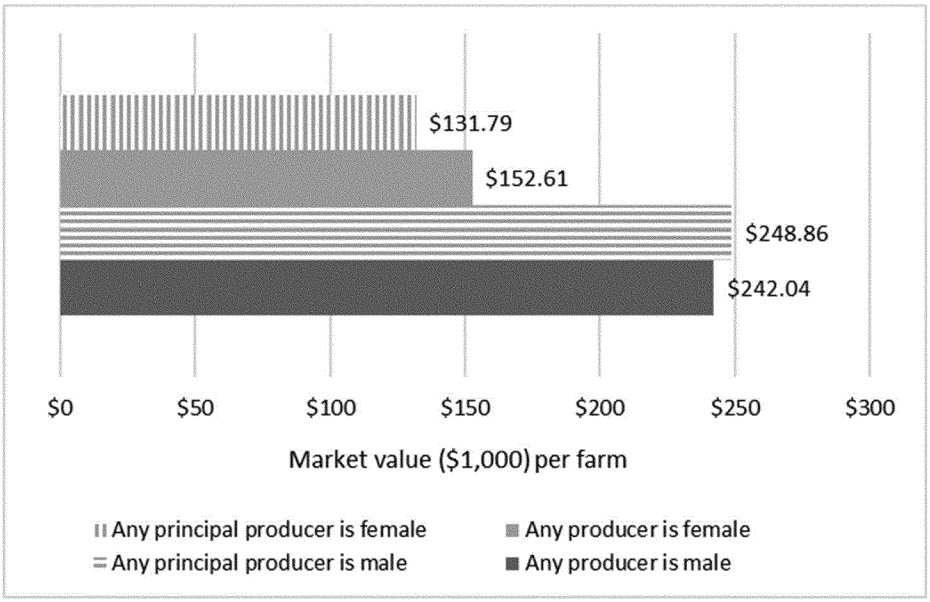
The regression analysis used above to study the effect of sex on prices received in livestock and poultry markets also found a statistically significant negative relationship between age of a farm operator and price received in poultry and owned-hog markets, as well as a statistically significant negative relationship between the experience of a farm operator and price received in the contract hog market. That is, as producers and growers age in the owned-hog and poultry markets and gain experience in the contract hog market, average price received declines. However, the same finding was not evident in cattle markets, where the relationship between increasing producer age and price is positive and statistically significant.

Gender is also a basis of discrimination in livestock and poultry markets. According to the 2017 Census, livestock and poultry operations where principal operators are female received significantly lower market value for the livestock and poultry they sell. Female principal operators in livestock and poultry earned 53 cents per operation for every dollar earned by male principal operators per operation. By comparison, in the broader U.S. population, females earn 77 to 82 cents for every dollar earned by men in

[52] From the Agricultural Census data, some farmers who produce under production contracts also report some owned production as well.

2022.[53] Figure 7 shows that the difference in livestock and poultry sales by gender is about $117,000 less per operation for female principal operators, or 47 percent less, compared to male principal-operated farms. Disproportionately more female operators are found in the lower income classes relative to males, and a disproportionately higher number of male operators are found in the highest income classes. The value of livestock and poultry production per total acres owned by males and females is $0.22 per acre for males and $0.18 per acre for females, or $0.82 per acre for female operators relative to every $1 per acre earned by male operators. Together, these data suggest that female producers in livestock and poultry markets achieve lesser economic outcomes than male producers.

Figure 7. Market Value of Livestock, Poultry, and Their Products Per Farm by Gender



Data source: 2017 Agricultural Census, National Agricultural Statistical Service, USDA.

Producers have also been targeted by processors that discriminate or retaliate against them for forming or being members of a cooperative because of the check on dominant firm bargaining power that cooperatives provide.[54] Growers and experts on agricultural cooperatives have reported numerous instances of live poultry dealers taking adverse actions against producers for their participation in agricultural cooperative activities.[55]

Regulated entity resistance to producer cooperatives is not difficult to understand—and indeed has been the basis for congressional action in the past. The increased bargaining power that cooperatives give to their members makes them a target for opposition or curtailment by regulated entities. In a market characterized by concentration of larger market intermediaries, cooperatives [56] can assist producers in promoting equal access to the market

[53] The Pew Research Center. March 1, 2023. ''The Enduring Grip of the Gender Pay Gap.'' Accessed at *https://www.pewresearch.org/social-trends/2023/03/01/the-enduring-grip-of-the-gender-pay-gap/* on 09–25–2023, and World Economic Forum. July 2023. Global Gender Gap Report 2023 Accessed at WEF_GGGR_2023.pdf (*weforum.org*) on 09–225–2023.

[54] USDA, Publications for Cooperatives, available at *https://www.rd.usda.gov/resources/publications-for-cooperatives* (See generally USDA's published research reports that document the history and importance of agricultural cooperatives that allow farmers to negotiate collectively for prices on product either sold or bought by input or buyer entities. For example, USDA in *Farm Bargaining Cooperatives: Group Action, Greater Gain* (1994) describes one harrowing instance in which members of a cooperative initially hesitated in bringing a complaint against a processor that allegedly punished them by refusing to buy their fruit due to their association with the cooperative; but eventually successfully brought the complaint and, after a lengthy legal process, won punitive damages and the processor's agreement to buy product); Vaheesan, S. and Schneider, N., 2019. Cooperative Enterprise as an Antimonopoly Strategy. *Penn St. L. Rev., 124,* p.1. Accessed at *https://elibrary.law.psu.edu/cgi/viewcontent.cgi?article=1000&context=pslr* (Oct. 2023).

[55] *Baldree* v. *Cargill, Inc.* and *United States* v. *Cargill, Inc., et al.,* 758 F.Supp.704 (M.D.Fla. 1990). *Arkansas Valley Industries, Inc., Ralston Purina Company, and Tyson's Foods, Inc.,* 27 Ag. Dec. 84 (January 23, 1968), and *In Re: Curtis Davis, Leon Davis, and Moody Davis d/b/a Pelahatchie Poultry Company,* 28 Ag. Dec. 406 (April 3, 1969).

[56] For the purposes of this preamble, a cooperative is an incorporated or unincorporated association of producers, with or without capital stock, formed for mutual benefit of its members. Farm cooperatives are formed under State, not Federal law, even though cooperatives have Federal protections. *See* James B. Dean & Thomas Earl Geu, *The Uniform Limited Cooperative Association Act: An Introduction,* 13 Drake J. Agric. L. 63, 67 (2008) (''There is, however, no single type of cooperative. Although much of the law that has developed around cooperatives has developed with respect to agricultural cooperatives, cooperatives exist in many areas . . . including housing, insurance, banking, health care, and retail sales, among others.''). Cooperatives can both be buyers and sellers of agricultural products. Cooperatives made up of sellers, because they jointly fix the prices of their goods, are legally permitted to market the products they produce when the cooperative organization meets the requirements of the Capper-Volstead Act (see 7 U.S.C. 291)7 U.S.C. 291) or the Clayton Act (see 15 U.S.C. 17).15 U.S.C. 17).

and enhance the bargaining power of smaller producers. At the same time, cooperatives are responsive to the needs of regulated entities and the market for greater volume, as opposed to negotiating with many smaller producers.[57] Yet precisely that presence of enhanced bargaining power, which cooperatives give to their members, makes them a target for opposition or curtailment by regulated entities. Congress has affirmed that cooperatives are necessary to protect the marketing and bargaining position of individual farmers and that interference with this right is not only contrary to the public interest but damaging to the free market.[58] As stated in the Congressional Record ''. . . wherever waste and uneconomic practices are discovered they should be eliminated, and whenever improvement can be made by cooperative effort these improvements should be sanctioned and adopted by those interested in our marketing system. . . .'' [59]

Producers have indicated to AMS that increased use of cooperatives is necessary because of the rise of abusive conduct aggravated by concentration in the markets and the decline in marketing options for smaller producers. For example, small cattle producers have expressed their concern to AMS about packers' disparate treatment of large and small producers. Large packers have commonly shown limited interest in dealing with producers that operate on a smaller capacity. Packers often prefer to buy large numbers of animals at once to lower transaction costs,[60] and if a single producer is unable to meet such demand, that producer is unable to compete in the industry. Smaller livestock producers can join together through cooperatives to achieve scale and meet buyers' volume requirements. Thus, cooperatives can help smaller producers gain business they would otherwise be unable to compete for in light of the current market structure. Moreover, Congress has encouraged the formation of agricultural cooperatives and, under the AFPA, has provided enhanced protection for them in the marketplace. Given that policy and statutory judgment, AMS interprets the Act to reinforce that objective. Accordingly, discriminating against a cooperative, absent a legitimate basis set forth under this final rule, is unjust and violative of the Act.

Additionally, cooperatives counterbalance the ability of regulated entities to exert market power against smaller or more vulnerable producers. Facing the threat of such a counterbalance, regulated entities have over time stymied producers' ability to form and utilize cooperatives. AMS has heard numerous reports of regulated entities terminating growers' or producers' contracts for their attempts to form cooperatives, as well as reports of the chilling effect such action has on any future attempts to do so.[61] More recently, cooperatives in the cattle sector have been frustrated in their effort to negotiate collectively. In recent years, the number of livestock and poultry cooperatives has declined, as shown in the figure below. While many reasons for that decline are unconnected to the discrimination prohibited in this rule, AMS believes cooperatives serve a crucial function in the marketplace and need protection against unjust discrimination by regulated entities. This final rule will protect producers who wish to form cooperatives and will strengthen the marketing and bargaining position of smaller or more vulnerable producers by enabling them to pool resources, coordinate, compete more effectively, and negotiate for fair and appropriate terms in the open market without fear of prejudice or discrimination from larger market intermediaries.

[57] At least some of the drafters of the Act fully expected the Act to be consonant to the goals of cooperatives: ''My own conviction is that the cooperative effort of producers and consumers to get closer together in an effort to reduce the spread between them is the most favorable tendency of our time, so far as the question of marketing and distribution is concerned.'' 61 Cong. Rec. 1882 (1921).

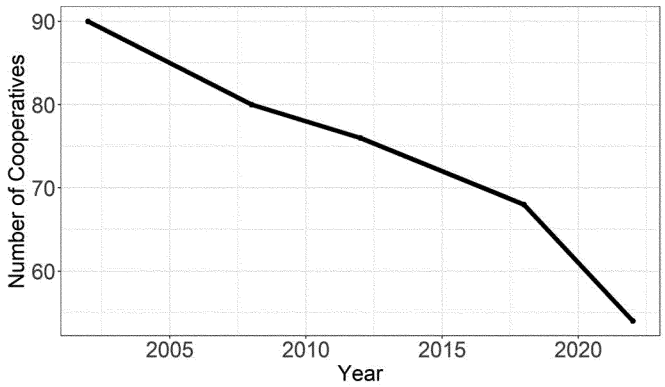
[58] 7 U.S.C. 2301.

[59] 61 Cong. Rec. 1882 (1921).

[60] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops, Exploring Competition Issues in Agriculture Livestock Workshop: A Dialogue on Competition Issues Facing Farmers in Today's Agricultural Marketplaces, Fort Collins, Colorado August 27, 2010. Available at *https://www.justice.gov/sites/default/files/atr/legacy/2012/08/20/colorado-agworkshop-transcript.pdf*.

[61] United States Department of Justice, United States Department of Agriculture, Public Workshops Exploring Competition in Agriculture: Poultry Workshops, (2010), available at *https://youtu.be/8QJ_K06lp5M?si=VGhP8lzw3f6tdM4B&t=305; https://youtu.be/8CvEGyMQ9v8?si=_tvtJVtlNmWDxedQ&t=3675; https://youtu.be/8QJ_K06lp5M?si=VGhP8lzw3f6tdM4B&t=305* (In which poultry growers discussed numerous instances of regulated entities terminating their contracts, reducing the quality of their feed, or otherwise intimidating them for participating in cooperative activities).

Figure 8: Decline in the number of livestock and poultry cooperatives in 2000–2022



Data source: "Publications for Cooperatives," USDA Rural Development, available at https://www.rd.usda.gov/resources/publications-for-cooperatives (Number of livestock and poultry cooperatives, produced from compiling internal USDA records, including from directories and public documents from 2000 – 2022. Number summarized shows the number of active cooperatives in the 5-year interval, e.g.: for 1992, from 1990 to 1995; for 1997, from 1993 – 2000).

Numerous public comments on the proposed rule supported the prohibition of undue prejudice based on protected bases such as those described above. In expressing support for the proposed ''market vulnerable individual (MVI)'' approach to addressing undue prejudices, several agricultural advocacy groups recommended that AMS explicitly enumerate protected bases in its definition of MVI. MVI, as defined in the proposed rule, is a person who is a member, or who a regulated entity perceives to be a member, of a group whose members have been subjected to, or are at heightened risk of, adverse treatment because of their identity as a member or perceived member of the group without regard to their individual qualities. The organizations said these protected bases should include, but not be limited to, the protected classes of race, color, national origin, religion, sex, sexual orientation, disability, age, income derived from a public assistance program, and political beliefs.[62] An agricultural advocacy group commented in support of a protected-bases approach, saying that ''fair access to markets for growers, farmers, and ranchers should be based on their farming and business skills, not on their membership in any of the above groups.'' [63] Another advocacy group added that defining protected bases ''will be an appropriately flexible concept with which to enforce enhanced protections against discrimination in the marketplace.'' [64] The group continued: ''Given the history of discrimination that farmers of color have faced over the course of American history, these producers should not be made to relitigate their status as market vulnerable in any given complaint.'' [65]

Multiple commenters from the meat and poultry industry who opposed the MVI approach nevertheless indicated that they would support rules targeting discrimination on specific prohibited bases.[66] A livestock industry association said discrimination on these types of bases is ''reprehensible and should be remediated using the appropriate legal avenues.'' [67] Several national and State farm bureaus expressed support for the rule's action to protect producers facing undue prejudice and unjust discrimination.[68]

[62] Government Accountability Project, Comments on Proposed Rule: Inclusive Competition and Market Integrity, (AugJan. 2022), *https://www.regulations.gov/comment/AMS-FTPP-21-0045-042720232*), *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0427* (Describing instances in which some producers described racially prejudicial treatment received from regulated entities, including requirements to do additional work, mockery, and exploitative behavior). Farm Action, Comments on Proposed Rule: Inclusive Competition and Market Integrity, (AugJan. 20232), *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0435* (Listing Supreme Court and lower court cases finding these forms of discrimination to be essentially unjust).

[63] Agricultural Advocacy Group. ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0434. https://www.regulations.gov/comment/AMS-FTPP-21-0045-0434.*

[64] Agricultural Advocacy Group. ''Comment on AMS–FTPP–21–0045: Inclusive Competition and Market Integrity Under the Packers and Stockyards Act,'' available at *Regulations.gov.*

[65] Agricultural Advocacy Group. ''Comment on AMS–FTPP–21–0045: Inclusive Competition and Market Integrity Under the Packers and Stockyards Act,'' available at *Regulations.gov.*

[66] *See, e.g.,* Meat Industry Trade Association, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424;* Industry Trade Association, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-04249; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424* Live Poultry Dealer;, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0419.*

[67] Industry Trade Association, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0418.*

[68] *See, e.g.,* Farm Bureau, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0426;* Other Association or Non-Profit, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0416; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0426;* Other Association or Non-Profit, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0416; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0416;* Other Association or Non-Profit, ''Comment

Continued

Discrimination on the bases of race, color, religion, national origin, sex (including sexual orientation and gender identity),[69] disability, marital status, or age is recognized throughout economic markets as impermissible, yet commonly occurring, bases for discrimination.[70] AMS recognizes the other Federal laws and authorities that justify these bases, finds that these bases are consistent with its understanding drawn from complaints and in the field, and accordingly adopts these bases as part of this rule.[71] Removing prejudicial barriers to the market will enhance producers' economic bargaining power, support investment in rural America, assure the next generation that taking over the farm can be a wise economic decision, and otherwise enhance economic opportunity and vitality in communities facing higher business and labor market concentration and the conduct addressed by this rule.

AMS finds that discrimination continues to occur through adverse actions described in the inexhaustive list offered in the final rule. The list includes offering contract terms that are less favorable than those generally or ordinarily offered, refusing to deal, performing under or enforcing a contract differently than with similarly situated producers, requiring modifications to contracts on terms that are less favorable than the existing contract with the covered producer or only offering to renew contracts on terms that are less favorable than those of the existing contract with the covered producer, and terminating or not renewing a contract.

As discussed further in Section VII—Comment Analysis, producers have indicated that regulated entities continue to engage in these types of discriminatory actions.

ii. Retaliation as Discrimination

Many producers across all animal species have expressed concerns about being retaliated against for engaging in legitimate business and advocacy activities inextricably linked to livestock and poultry markets. Contract poultry growers and hog producers have expressed to USDA that they have experienced—and consistently fear—retaliation from live poultry dealers and packers for communicating with each other, with their dealer's and packer's competitors, and with governmental officials, as well as for forming associations and cooperatives, exercising contract or legal rights, or being a witness in proceedings against the regulated entity.[72] Cattle producers have similarly expressed fear that packers will refuse to offer bids on livestock, or purchase livestock from disfavored producers, and they have highlighted other, more subtle retaliatory behaviors, like delaying delivery or shipment, for engaging in similar activities.[73] Producers believe the ability to communicate with others, to form associations and cooperatives, to exercise legal rights, and to witness against regulated entities are critical to free participation in the livestock and poultry markets. Inhibition of these freedoms jeopardizes producers' ability to obtain the full value of their livestock and poultry products and services. Indeed, producers have reported to AMS over the years that retaliation by regulated entities—or threat thereof—for producers' exercise of these rights is significant enough to place a producer's entire farm at risk. This reported conduct is the type of behavior AMS aims to prohibit through this rulemaking.[74]

This is a persistent problem. As recently as April 2022, threats and fear of retaliation interfered with witness testimony at each of the House and Senate Agriculture Committees' hearings on livestock competition practices. In his opening remarks, House Agriculture Committee Chair David Scott noted, ''We were supposed to have a 4th witness, a rancher, on our panel, but due to intimidation and threats to this person's livelihood, to this person's reputation, they chose not to participate out of fear. Witness intimidation is unacceptable. . . .'' [75]

The day before, Senator Deborah Fischer had stated, ''I wish we had a Nebraska producer here, but as is noted in their letter, none of our producer members we encouraged to testify were willing to put themselves out front for fear of possible retribution from other market participants, an unfortunate reality of today's cattle industry.'' [76]

In response to the proposed rule, commenters expressed support and opposition for the proposal to establish prohibitions against retaliatory practices. Several industry associations opposed the proposed rule, indicating it is duplicative and therefore not necessary. These commenters contended the conduct addressed in the

on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0441.*

[69] 140 S. Ct. at 1737, available at *https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf* (The Supreme Court has held that the prohibition on discrimination ''because of . . . sex'' covers discrimination on the basis of gender identity and sexual orientation).

[70] See, *e.g.,* U.S. Department of Justice, ''The Attorney General's 2021 Annual Report to Congress on Fair Lending Enforcement,'' available at *https://www.justice.gov/media/1259491/dl?inline.*

[71] 15 U.S.C. 1691; 7 U.S.C. 2301 *et seq.* (See below section, Provisions of the Final Rule—Undue Prejudice and Unjust Discrimination, that discusses the adoption of other Federally listed bases as part of this rule).

[72] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Poultry Workshop, May 21, 2010, Alabama A&M University Normal, Alabama. Available at *Poultry Workshop Transcript (justice.gov)* (*https://youtu.be/j11GXzvA7u0?si=6YNtz2SJH5T81FJZ&t=2656; https://youtu.be/8QJ_K06lp5M?si=C1HA0i84opqaoIn8&t=1051*).

[73] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Livestock Industry, August 27, 2010, Fort Collins, Colorado, Available at *https://www.justice.gov/atr/events/public-workshops-agriculture-and-antitrust-enforcement-issues-our-21st-century-economy-10* (*https://youtu.be/j11GXzvA7u0?si=6YNtz2SJH5T81FJZ&t=2656https://youtu.be/Ygerhjjp0Is?si=WMS4YGdAjNtIsBgH&t=1833; https://youtu.be/tF4Dr-O-l8s?si=BZJQYN-rkp-qqvjN&t=1158;* numerous producers, including the previous president of the Kansas Cattlemen's Association, discussed instances in which they experienced retaliation from the largest packers. For example, one producer described how they decided to allow other packer buyers first opportunity to buy cattle in response to the packer not selecting them for a contracting agreement. The producer said that the packer told ''his buyer to quit coming into our yard.'' Another producer agreed, describing an incident in which they perceived that one of the largest packers possibly retaliating against them for previous litigation: the producer described how the packer hung a ''No Trespassing'' sign on the producer's door and began offering a ''five-minute window'' to buy cattle).

[74] Lina Khan, ''Obama's Game of Chicken,'' *Wash. Monthly* (2012), *https://washingtonmonthly.com/magazine/novdec-2012/obamas-game-of-chicken/* (Recounting testimony by Tom Green, an Alabama farmer who contested a contract and lost their farm: ''We did not give up a fundamental right to access the public court . . . which is guaranteed by our Constitution, regardless of price. I had flown too many combat missions defending that Constitution to forfeit it. It was truly ironic that protecting one right, we lost another. We lost the right to property''). Isaac Arnsdorf, ''How a Top Chicken Company Cut Off Black Farmers, One by One,'' Propublica (June 26, 2019), *https://www.propublica.org/article/how-a-top-chicken-company-cut-off-black-farmers-one-by-one* (Describing how one farmer participated in the 2010 USDA–DOJ workshops and ''. . . never got another chicken after going to that meeting over there in Alabama. . . They put me slap out of business'').

[75] House Chair David Scott D–GA, opening remarks, U.S. House, Committee on Agriculture, ''An Examination of Price Discrepancies, Transparency, and Alleged Unfair Practices in Cattle Markets,'' April 27, 2022, (14 min: 24 sec), available at *https://anchor.fm/houseagdems/episodes/An-Examination-of-Price-Discrepancies--Transparency--and-Alleged-Unfair-Practices-in-Cattle-Markets-e1hpvo8/a-a7r40dk.*

[76] U.S. Senate Committee on Agriculture, Nutrition, and Forestry, ''Legislative hearing to review S. 4030, the Cattle Price Discovery and Transparency Act of 2022, and S. 3870, the Meat and Poultry Special Investigator Act of 2022,'' April 26, 2022, (1 hour 39 min), available at *https://www.agriculture.senate.gov/hearings/legislative-hearing-to-review-s-4030-the-cattle-price-discovery-and-transparency-act-of-2022-and-s3870-the-meat-and-poultry-special-investigator-act-of-2022.*

proposed rule is not a widespread problem and is already prohibited under the Act. Other commenters supported the rule. One organization cited a recent anonymous survey of contract growers it had conducted. Multiple respondents had experienced retaliation from integrators and said integrators regularly terminate contracts with farmers who engage in whistleblowing activities. These contract terminations leave growers with substantial debt tied up in specialized, single-use structures built as a condition of their contractual agreements. Although comments in response to the proposed rule differ greatly regarding the need for this rule, commenters generally do not disagree that discriminatory and retaliatory conduct is harmful to producers and offers no procompetitive benefits. For these reasons, AMS needs to use its statutory authority to provide a regulatory framework for prohibiting retaliatory behavior by regulated entities against covered producers. Establishing regulatory protections to prohibit regulated entities from retaliating against producers engaging in lawful activity will help promote fair trade practices and competitive markets.

In recent years, producers have been increasingly vulnerable to harms from retaliatory behavior due to the market power afforded regulated entities under contracts that can reach further down into livestock and poultry production and/or are bilateral. This is in contrast to past circumstances where these relationships were intermediated through an institution such as a stockyard (auction) subject to heightened regulatory duties around nondiscrimination.

As regulated entities have obtained greater control over the input industries, particularly in poultry, producers are increasingly dependent upon regulated entities for success. That dependence, in combination with high levels of debt, leaves producers vulnerable to the retaliation that regulated entities can exact through input distribution and in other ways. Growers have for years reported punitive delivery of inputs to deter their exercise of a wide range of legal rights and remedies that would enable them to earn the full value of their services.[77] [78]

Based on complaints and industry experience, AMS is aware that retaliation by regulated entities may take many forms, such as canceling contracts, selectively enforcing contract terms, refusing to deal or negotiate, or otherwise impairing an individual's or group of producers' ability to operate.[79] In contrast, in more competitive markets, producers facing retaliation can more easily avoid or mitigate adverse impacts by simply finding other entities with whom to do business. Without choices, producers are at the mercy of the types of abuses the Act was designed to prevent—market abuses that inhibit producers' ability to get the full value of their products and services. Ultimately, regulated entities may retaliate for various reasons, but none have any role in or benefit to the competitive functioning of the market.[80]

As discussed below in Section VII—Comment Analysis, in response to the proposed rule, commenters expressed extensive agreement with the need to establish prohibitions against retaliatory practices.

iii. Deceptive Practices

The Packers and Stockyards Act has long recognized that integrity and honesty are vital to the marketing of livestock and, therefore, to the efficiency with which these markets supply meat to the American consumer.[81] This rulemaking is a response, in part, to the range of complaints lodged with USDA, Congress, and the media over the years regarding inaccurate, incomplete, or otherwise false or misleading statements, or omission of material information that affects decision-making or access to markets by producers. These complaints reflect, in part, changed industry contracting norms or a market environment where the prevalent norms result in more acute harms to producers. For example, packers and industry representatives have routinely indicated that producers may choose the form of pricing mechanism for their transactions. However, as cash-negotiated markets have declined, producers have increasingly complained to USDA that they are not provided such a choice, and are commonly given a take-it-or-leave-it offer to buy their cattle off of a pricing formula provided by the company.[82] Producers have complained they have been told that packers refuse to buy their cattle on the grounds they are not of sufficiently high quality or that formula market arrangements are necessary to incentivize such quality, when the cattle being offered were of no less quality than those the packer procured under other marketing arrangements.[83]

Poultry producers have complained to USDA over the years regarding unfavorable provision of inputs made to certain producers despite statements by live poultry dealers that there are no differences in treatment. Producers have also complained to USDA of terminations, suspensions, or reductions in flocks on pretexts—*i.e.,* on the provision of false or misleading information such as claims of animal

[77] U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Poultry Workshop, May 21, 2010, Alabama A&M University Normal, Alabama. Available at *Poultry Workshop Transcript (justice.gov);* see also Lina Khan, ''Obama's Game of Chicken,'' *The Washington Monthly,* Nov. 2012, available at

[78] Oscar Hanke, ed., *American Poultry History,* 1823–1973 (Madison, Wisc., 1974), 384–85. Fite, Cotton Fields No More, 201; Peck, A, (2006), ''State regulation of production contracts.'' University of Arkansas National Center for Law Research and Information, available at *http://nationalaglawcenter.org/wp-content/uploads/assets/articles/peck_contractregulation.pdf;* Stephen F. Strausberg, *From Hills and Hollers: Rise of the Poultry Industry in Arkansas* (Fayetteville, Ark., 1995), 136; Heffernan, W. D., (1984), *Constraints in the U.S. poultry industry. Research in Rural Sociology and Development,* 1, 237–260 (Researchers have documented the increased incidence of producers' complaints and decreasing satisfaction in the industry beginning in the 1980s, which coincided with increasing concentration of the industry. Weinberg writes how, in 1960, 19 firms processed 30 percent of total US poultry processed and that producers who entered the business tended to achieve upward mobility. In the 1970s, only 8 firms processed the same percent of poultry. This trend accompanied an increased incidence of grower dissatisfaction. Gordy notes how ''loss of independence and lower incomes caused some growers to become disenchanted.'' Fite observed how poultry farmers were ''controlled and sometimes exploited by their suppliers.'' Peck notes how dissatisfaction by growers prompted State attorneys general to propose a 3-day right of review in a model producer protection act in the early 2000s. In 2010, the USDA and DOJ hosted a series of workshops in which growers raised concerns about retaliation in the industry. These trends, which occurred alongside increased productivity gains and use of technology, coincided with exits in the industry. As Weinberg documented, in Georgia, in 1950, 1176 Hall County farms sold 6.8 million chickens; in 1992, only 192 sold 44.3 million chickens).

[79] See, *e.g.,* U.S. Department of Justice & U.S. Department of Agriculture, Public Workshops Exploring Competition in Agriculture, Poultry Workshop, May 21, 2010, Alabama A&M University Normal, Alabama, available at *https://youtu.be/8CvEGyMQ9v8?t=3135* (in which poultry growers described how companies seemingly arbitrary mandated expensive upgrades).

[80] Fehr, Ernst, and Simon Gächter. ''Fairness and retaliation: The economics of reciprocity.'' *Journal of economic perspectives* 14, no. 3 (2000): 159–181.

[81] *See, e.g., Midwest Farmers* v. *United States,* 64 F. Supp. 91, 95 (D. Minn. 1945); *In re: Frosty Morn Meats, Inc.,* 7 B.R. 988, 1020 (M.D. Tenn. 1980).

[82] Other Association or Non-Profit, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0423.*

[83] C. Robert Taylor, ''Harvested Cattle, Slaughtered Markets,'' April 27, 2022, 7–9, available at *https://www.antitrustinstitute.org/work-product/aai-advisor-robert-taylor-issues-new-analysis-on-the-market-power-problem-in-beef-lays-out-new-policy-framework-for-ensuring-competition-and-fairness-in-cattle-and-beef-markets/.*

welfare contractual violations—when other reasons may exist for the adverse actions, including the discrimination and retaliation noted previously, or other unreasonable bases, such as a preference for family or friends of the local agent of a live poultry dealer or for a poultry grower connected to a senior executive of a live poultry dealer.[84] Contract termination puts the grower at severe risk of significant economic loss. A production broiler house often has significant long-term financial obligations. The potential loss includes not only the loss of production income, but financing for construction, which often comes from mortgages on the grower's farm or family home. Pretextual cancellation may make even the sale or transfer of the broiler production house impossible because purchasers may be unable to determine whether the broiler houses have value.

As discussed in Section VII—Comment Analysis, comments underscored the need to address deceptive practices in this rulemaking.

III. Authority

Congress enacted the Act to promote fairness, reasonableness, and transparency in the marketplace by prohibiting practices that are contrary to these goals. AMS is issuing these regulations under the Act's provisions prohibiting undue prejudice, unjust discrimination, and deception to provide for clearer, more effective standards to govern the modern marketplace and to better protect, through compliance and enforcement, individually harmed producers.

Enacted in 1921 ''to comprehensively regulate packers, stockyards, marketing agents and dealers,'' [85] the Act, among other things, prohibits actions that hinder integrity and competition in the livestock and poultry markets. Section 202(a) of the Act states that it is unlawful for any packer, swine contractor, or live poultry dealer to engage in or use any unfair, unjustly discriminatory, or deceptive practice or device.[86] Section 202(b) of the Act states that it is unlawful for any packer, swine contractor, or live poultry dealer to make or give any undue or unreasonable preference or advantage to any particular person or locality, or subject any particular person or locality to any undue or unreasonable prejudice or disadvantage in any respect.

Section 407 of the Act provides that the Secretary ''may make such rules, regulations, and orders as may be necessary to carry out the provisions of this [Act].'' (7 U.S.C. 228(a)) The Secretary has delegated the responsibility for administering the Act to AMS. Within AMS, the Packers and Stockyards Division (PSD) of the Fair-Trade Practices Program has responsibility for the day-to-day administration of the Act. The current regulations implementing the Act are found in title 9, part 201, of the CFR. Therefore, based on the authority delegated to USDA by Congress to administer the Act, AMS is promulgating this rulemaking to amend part 201 to specifically clarify that discriminatory, deceptive, and retaliatory conduct, as defined in this rule, are violations of the Act.

Executive Order (E.O.) 14036, ''Promoting Competition in the American Economy'' (86 FR 36987, July 9, 2021), directs the Secretary to further the vigorous implementation of the Act. Accordingly, this final rule addresses the unfair treatment of farmers and improves competitive conditions in markets. This rule adds clarity to USDA's regulations concerning unjustly discriminatory practices, deceptive practices, and undue or unreasonable prejudices or disadvantages. E.O. 14036 underscored that ''it is unnecessary under the... Act to demonstrate industry-wide harm to establish a violation of the Act and that the 'unfair, unjustly discriminatory, or deceptive' treatment of one farmer'' violates the Act. Among other policy goals in the E.O., this final rule is specifically intended to address the unfair treatment of farmers and make it easier for them to garner the full value of their animals. The Act is a remedial statute enacted to address problems faced by farmers, producers, and other participants in the markets for livestock, meats, meat food products, livestock products in unmanufactured form, poultry, and live poultry; to protect the public from predatory practices; and to help ensure a stable food supply. Thus, as academics and courts have noted, the Act has ''tort-like provisions that are concerned with unfair practices and discrimination'' that fulfill a ''market facilitating function,'' which Congress designed to prevent ''market abuse.'' [87] AMS interprets and implements the Act to achieve its core statutory purposes.[88]

IV. Summary of the Proposed Rule

In the October 2022 proposal, AMS proposed amending 9 CFR 201 by adding a new subpart O, titled ''Competition and Market Integrity,'' and containing §§ 201.300 through 201.390. AMS proposed adding a Definitions section, § 201.302, containing the terms *covered producer, livestock producer, market vulnerable individual,* and *regulated entity.*

AMS also proposed adding § 201.304, titled ''Undue prejudices or disadvantages and unjust discriminatory practices,'' to prohibit regulated entities from discriminating against a market vulnerable individual or a cooperative, detailing in proposed paragraph (a) types of prohibited actions. Paragraph (b) of the proposed regulation would prohibit regulated entities from retaliating against a covered producer because of the covered producer's participation in a producer association, protected activities, including assertion of rights under the Act, and lawful communication. Proposed paragraph (b) also provided examples of prohibited retaliatory actions. Proposed paragraph (c) included a requirement that regulated entities retain records of compliance with paragraphs (a) and (b) for no less than five years from the date of record creation.

AMS also proposed adding § 201.306, titled ''Deceptive practices,'' prohibiting a regulated entity from employing a false or misleading statement or omission of material information necessary to make a statement not false or misleading during contract formation,

[84] *Wheeler* v. *Pilgrim's Pride,* 536 F.3d 455 (5th Cir. 2008); United States Department of Justice, United States Department of Agriculture, Public Workshops Exploring Competition in Agriculture: Poultry Workshop May 21, 2010; Normal, Alabama, *https://www.justice.gov/sites/default/files/atr/legacy/2010/11/04/alabama-agworkshop-transcript.pdf,* last accessed 8/14/23.

[85] Hays Livestock Comm'n Co. v. Maly Livestock Comm'n Co., 498 F.2d 925, 927 (10th Cir. 1974).

[86] 7 U.S.C. 192(a).

[87] Herbert Hovenkamp, ''Does the Packers and Stockyards Act Require Antitrust Harm?'' (2011). Faculty Scholarship at Penn Carey Law. 1862. *https://scholarship.law.upenn.edu/faculty_scholarship/1862* (''subsections (a) and (b) appear to be tort-like provisions that are concerned with unfair practices and discrimination, but not with restraint of trade or monopoly as such''); Peter Carstensen, The Packers and Stockyards Act: A History of Failure to Date, CPI Antitrust Journal 2–7 (April 2010) (''Congress sought to ensure that the practices of buyers and sellers in livestock (and later poultry) markets were fair, reasonable, and transparent. This goal can best be described as market facilitating regulation.''); Michael C. Stumo & Douglas J. O'Brien, Antitrust Unfairness vs. Equitable Unfairness in Farmer/Meat Packer Relationships, 8 Drake J. Agric. L. 91 (2003); Michael Kades, ''Protecting livestock producers and chicken growers,'' Washington Center for Equitable Growth (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf* (''Section 202's prohibitions on unjust discrimination and undue preference are not limited to conduct that destroys or limits competition or creates a monopoly. These provisions address conduct that impedes a well-functioning market and deprives livestock and poultry producers of the true value of their animals. Taken together, these provisions seek to prevent market abuses.'').

[88] See *Bowman* v. *U.S. Dep't of Agric.,* 363 F.2d 81 at 85 (5th Cir. 1966).

performance, and termination. Section 201.306 also proposed to prohibit a regulated entity from providing false or misleading information concerning a refusal to contract. The proposal was designed to prohibit regulated entities from specified deceptive practices in contracting, which are of particular concern because of the power of the regulated entities over their vertical contracting relationships. As stated in the proposal, AMS intended this proposed regulation to address broad areas of specific concern, not exhaustively identify all deceptive practices that would violate sec. 202(a) of the Act.

Finally, AMS proposed adding § 201.390, titled ''Severability.'' This provision was intended to inform reviewing courts that if any provision of subpart O was declared invalid, or if the applicability of any of its provisions, or any components of any provisions, to any person or circumstances was held invalid, the validity of the remaining provisions of subpart O or their applicability to other persons or circumstances would not be affected. Severability provisions are typical in modern AMS regulations. AMS regulations often cover several different topics in a subpart. This provision was added because the regulations in subpart O are designed to address several different types of violations under the Act. Because these violations address similar underlying developments in the livestock and poultry markets—namely, abusive practices facilitated by increased vertical integration and horizontal concentration—these violations were suitable for joining in a single rulemaking. However, each could be viewed as its own stand-alone rulemaking and therefore should be severable.

Upon consideration of public comments on the proposed rule, AMS modified some of its proposed provisions to derive this final rule. These changes are outlined below.

V. Changes From the Proposed Rule

AMS is making the following changes to the proposed rule based on the agency's analysis of the issues raised by commenters.

A. Market Vulnerable Individual (MVI) to Prohibited Bases

With respect to the proposed regulations regarding undue prejudice and unjust discrimination, § 201.304, several commenters expressed concern that the definition of ''market vulnerable individual (MVI)'' as the basis for prohibiting undue prejudice and discrimination was too broad and ambiguous and could lead to an avalanche of litigation. To simplify this section, the final rule uses a delineated set of protected bases against undue prejudice and discrimination that were discussed in the proposed rule: race, color, national origin, religion, sex, sexual orientation, gender identity, age, disability, and marital status. These delineated bases reflect the Statement of General Policy Under the Packers and Stockyards Act published by USDA in 1968 (9 CFR 203.12(f)) and USDA's Conducted Programs Statement, and reflect a general congressional policy as indicated in other statutory sources (discussed below).[89] The final rule retains status as a cooperative as a protected basis against undue prejudice and discrimination, which reflects the principles set forth in the Agricultural Fair Practices Act of 1967.[90] (For the avoidance of doubt, AMS notes that discrimination against a member of a cooperative is prohibited under the provisions of paragraph (b)(2)(iii).) Accordingly, AMS has removed the term *market vulnerable individual* from the list of terms defined for subpart O in § 201.302.

AMS is adopting the aforementioned specific bases, as opposed to MVI, because the specific prohibited bases offer clearer, more workable standards to achieve the same goal set forth and specifically articulated in the proposed rule, but in a manner that will facilitate compliance by regulated entities and better enable producers to exercise their rights under the Act. As AMS explained in the proposed rule, the principal purpose of the MVI approach was to address prejudices in the marketplace against producers that are more vulnerable to such treatment and to stop unjust discrimination. AMS views vulnerability to adverse marketplace treatment to include, but not be limited to, exclusion or disadvantage on the basis of race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, or age, or on the basis of the covered producer's status as a cooperative. AMS initially adopted the MVI approach because it believed that the proposed rule's flexible approach to resolving marketplace vulnerabilities offered producers protection in an ever-evolving market. The proposed approach had the advantage of being responsive to the particular facts of given cases and particular markets over time.

As part of the rulemaking process, however, AMS sought comment on whether this was the best approach. AMS requested comment on whether it should ''delineate specific categories of vulnerable producers on the basis of membership in groups that have historically been subject to adverse treatment owing to racial, ethnic, gender, or religious prejudices.'' (87 FR 60010, Oct. 3, 2022) AMS also sought comment on ''whether this regulation should ban discrimination against specific classes, such as on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, age, disability, marital status, or family status. Such an approach would differ from the market vulnerable individual approach and would instead more closely follow the civil rights laws that prohibit prejudicial discrimination against certain protected classes.''

After considering the comments on both the MVI approach and on specific delineated bases, AMS determined that MVI is not sufficiently clear enough to meet the objectives of this regulation. The enumeration of specific prohibited bases provides more clarity and certainty by limiting the scope of the rule to prohibited adverse actions against all producers on the basis of their membership of a protected class, in line with existing civil rights requirements. Commenters, such as a meat industry trade association, a poultry industry trade association, and a live poultry dealer, criticized the proposed rule's MVI definition for being vague and ambiguous and potentially exposing their businesses to an unworkable standard that could potentially encompass a wide range of covered producers far beyond what the Agency appeared to be contemplating in the proposed rule. In contrast, these commenters indicated that an approach based on specific classes, such as race, sex, sexual orientation, or religion, would be clearer and would follow the precedent of civil rights laws already in place while protecting all producers.[91]

[89] 7 CFR 15d.3; U.S. Department of Agriculture, ''Nondiscrimination in Programs or Activities Conducted by the United States Department of Agriculture,'' 79 FR 41406, July 16, 2014.

[90] Public Law 90–288.

[91] *See, e.g.,* ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424;* ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-04249; https://www.regulations.gov/comment/AMS-FTPP-21-0045-0424;* ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://*

Continued

Several meat and poultry industry commenters who opposed use of the MVI approach stressed that they do not engage in discrimination on the specific bases set forth in this final rule and oppose such discrimination.[92]

Multiple agricultural advocacy organizations also expressed approval of these protected classes as the prohibited bases for discrimination when responding to the proposed rule's solicitation of responses on this issue, saying discrimination against individuals in these groups should be clearly recognized so those individuals do not have to continually prove discrimination and prejudice against them based on the characteristic that makes them vulnerable in the market. AMS agrees that the bases adopted in the final rule reflect genuine vulnerability to market exclusion and have no competitive benefit.

AMS also notes that some commenters interpreted the MVI approach as potentially providing protection to small producers on the basis that small producers were vulnerable to discrimination in the form of the same kinds of adverse treatment proposed to be prohibited in this rule. While AMS is sympathetic to the plight of small producers' challenges in accessing fair markets, AMS did not intend this rule to address those concerns (as also discussed below in Section VII—Comment Analysis). Basing the rule on a term that gave rise to such disparate interpretations underlined the necessity of utilizing the more specific bases set forth in the proposed rule's alternative formulation.

Additionally, AMS notes that these prohibited bases are now widely accepted standards of non-discrimination at USDA and in the U.S. economy more broadly. AMS adopted many of these as part of its 1968 Statement of General Policy.[93] Together with the Agricultural Fair Practices Act of 1967, these bases also apply to AMS enforcement of the Equal Credit Opportunity Act (ECOA) under the Act, to USDA programs through its Conducted Programs Statement, and, more recently, to the terms of USDA's debt relief under section 22007 of the Inflation Reduction Act.[94] The terms are also widely accepted bases in other laws that prohibit discrimination, such as in housing and employment.[95] The prohibited bases defined in the final rule have become so widely accepted as prohibited bases of discrimination that it would be notable and arbitrary for the Agency to pick some of the terms and not others. Quite simply, ''*unjust* discrimination'' and ''*undue* prejudices'' cannot be read but to include these widely accepted non-discrimination terms.

Accordingly, to achieve the same goal that the Agency set forth in the proposed rule through both MVI and the alternative formulation, AMS is now adopting the alternative formulation: race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, or age of the covered producer; or because of the covered producer's status as a cooperative.

B. Prohibited Actions Taken on a Prejudicial Basis

In § 201.304(a)(2), AMS made three changes to the provisions regarding prohibited actions taken on a prejudicial basis. First, in paragraphs (a)(2)(i) through (iii), AMS proposed to prohibit offering contracts that are less favorable than those generally or ordinarily offered, refusing to deal, and differential contract performance or enforcement, when each occurred on a prohibited basis. AMS is revising each of these provisions to provide clarity and uniformity across this final rule with respect to a comparison to similarly situated producers and also to ensure parallel language with the retaliation adverse actions under § 201.304(b)(3). Paragraph (a)(2)(i) is revised to read ''Offering contract terms that are less favorable than those generally or ordinarily offered to similarly situated producers; paragraph (a)(2)(ii) is revised to read ''Refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers''; and paragraph (a)(2)(iii) in the final rule is revised to read ''performing under or enforcing a contract differently *than with similarly situated covered producers*'' [emphasis added]. ''Similarly situated,'' is a phrase commonly used by commenters and by AMS in the proposed rule when discussing producer groups.[96] Including this concept in the final regulation provides more context for a comparison of what differential performance or enforcement would look like, and therefore provides more specificity to the regulation. This revision also mirrors a revision made to language in a similar provision in the retaliation section (§ 201.304(b)(3)(ii) and (iv)). The addition of ''with a covered producer'' in paragraph (a)(2)(ii)—Refusal to deal, is similarly designed to align with the parallel provision for paragraph (b)(3)(iv) as was set out in the proposed rule and retained in the final rule. The final rule adds ''on terms generally or ordinarily offered to similarly situated producers'' as well, in response to comments (as discussed below) to provide similar clarity of application that refusal to deal is not simply an absolute boycott or making a sham or nominal offer, but includes failure to bid, negotiate, and otherwise make a reasonable attempt to contract on terms generally or ordinarily offered to similarly situated producers *when done on the prohibited basis.*

Second, AMS is adding a new paragraph (a)(2)(iv), which prohibits—when it occurs on a prohibited basis—''requiring a contract modification or renewal on terms less favorable than similarly situated covered producers.''[97] The new provision expands on the concept encompassed in paragraph (a)(2)(i), which prohibits ''offering contract terms that are less favorable than those generally or ordinarily offered to similarly situated covered producers.'' The new provision prohibits regulated entities from making contract terms less favorable for producers once they are under contract and have incurred financial obligations because of that contract. The new provision mirrors a new provision

www.regulations.gov/comment/AMS-FTPP-21-0045-0419.

[92] See, *e.g.,* National Cattlemen's Beef Association, ''Comment on AMS–FTPP–21–0045: Inclusive Competitive and Market Integrity Under the Packers and Stockyards Act'' (received Jan. 17, 2023), available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0418* (Deception, discrimination, or retaliation on the basis of race, ethnicity, sexual orientation, gender identity, ability, religion/spirituality, nationality and/or socioeconomic status is reprehensible and should be remediated using the appropriate legal avenues, including legislative changes where necessary).)

[93] 9 CFR 203.12(f).

[94] USDA, Discrimination Financial Assistance Program, ''Eligibility,'' *https://22007apply.gov/eligibility.html* (last accessed Oct. 2023) (''This program covers discrimination based on different treatment you experienced because of: Race, color, or national origin/ethnicity (including status as a member of an Indian Tribe); Sex, sexual orientation, or gender identity; Religion; Age; Marital status; Disability; Reprisal/retaliation for prior civil rights activity'').'')

[95] See, generally, DOJ, Civil Rights Division. The Attorney General's Annual Report to Congress on Fair Lending Enforcement (2021), available at *https://www.justice.gov/d9/pages/attachments/2022/11/14/ecoa_report_2021_final_0.pdf* (In 2001 to 2021, there were 496 fair lending referrals to DOJ, of which 163 were on the basis of race and national origin. Other noted referrals, and then cases, in 2019 and 2020 were discrimination based on age and gender.)

[96] *See also Central Railroad Co. of New Jersey* v. *United States,* 257 U.S. 247 (1921) (''They can be held jointly and severally responsible for unjust discrimination only if each carrier has participated in some way in that which causes the unjust discrimination, as where a lower joint rate is given to one locality than to another similarly situated'').

[97] Proposed paragraph (a)(2)(iv), which prohibited termination or non-renewal of a contract on a prohibited basis, is renumbered in the final rule as paragraph (a)(2)(v).

added to the retaliation section (§ 201.304(b)(3)(iii)) in response to public comment on the proposed retaliation regulations. AMS also uses a similar approach in the retaliation section on refusing to deal (§ 201.304(b)(3)(iv)), as requested by public commenters, by adding ''with a covered producer on terms generally or ordinarily offered to similarly situated covered producers'' after ''deal,'' for the same reasons—this language helps prevent evasion. Commenters requested that AMS provide more protection so that regulated entities cannot formulate new ways of harming producers in contracting—a crucial component of a producer's financial well-being. Commenters suggested an additional provision regarding specific contract terms, including contract modification, be added to the regulations. While AMS did not adopt the suggested provision in whole, AMS recognizes the importance of specifically prohibiting unfavorable contract modifications or renewals that occur on a prohibited basis, considering the detrimental financial impact this can have on producers already under contract. In making these changes, the final rule provides a greater degree of specificity regarding the type of conduct the rule prohibits. AMS will review the facts and circumstances of each case and the regulated entity's justifications for any modification or renewal to determine whether the regulated entity has violated this rule.

Third, AMS is adding a new paragraph (a)(2)(vi), which prohibits regulated entities from taking ''any other action that a reasonable covered producer would find materially adverse.'' This provision represents a logical outgrowth from the proposed rule, which had indicated that the ''prejudice or disadvantage with respect to paragraph (a)(1) of this section includes the following actions.'' As AMS explained in the proposed rule, AMS believes that the type of harm to a producer will not be difficult to identify when it occurs based upon the facts and circumstances, and thus provided an exemplary list to aid in identification and enforcement under the rule. Such a list was not intended to be all encompassing. However, in response to comments, AMS has recognized that such an open-ended approach may create too much uncertainty and undermine compliance and enforcement. AMS is replacing the use of ''includes'' with an additional, more flexible provision that provides a broader yet not unlimited range of possible harms. AMS's approach is in response to comments that adverse treatment of producers by regulated entities can occur outside the confines of the contractual relationship. Such conduct could include, for example, interference by a regulated entity into regulatory matters of significant material importance to producers. Several public commenters wanted more producer protections incorporated into § 201.304(a)(2). This provision provides a broad and flexible approach to these prohibitions and allows for ''material'' to be determined by the facts and circumstances of each case while staying within the scope of the proposed rule's intent around harms to producers under unjust discrimination and undue prejudice deriving from adverse actions.

C. Exceptions to the Prohibited Bases

Commenters suggested that AMS include exceptions to the prohibition on undue prejudice and unjust discrimination. In response to these comments and the shift from MVI to identifying specific prohibited bases, AMS decided to provide specific exceptions from the prohibition in two circumstances. New § 201.304(a)(3) states that the following actions by a regulated entity do not prejudice, disadvantage, inhibit market access, or constitute adverse action under § 201.304(a)(1): (i) fulfilling a religious commitment relating to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry; (ii) a Federally-recognized Tribe, including its wholly or majority-owned entities, corporations, or Tribal organizations, performing its Tribal governmental functions.

In shifting from MVI toward specific prohibited bases, AMS identified the need to provide certain exceptions from the prohibition. The proposed MVI was a flexible standard that permitted the Agency to evaluate the facts and circumstances of a particular case and whether the exclusion or disadvantageous contracting arrangement was based on the characteristics of the producer. Specifying delineated prohibited bases provides greater clarity, yet in doing so, it eliminates a degree of flexibility that could be valuable in a small set of circumstances. Accordingly, the Agency is adopting two specific exceptions to recognize circumstances that do not give rise to unjust discrimination. AMS asked questions about both areas in the proposed rule, highlighting to commenters that the Agency recognized the potential for additional adjustments to be made in those areas.

First, AMS is providing a specific exception to recognize the important role ritual slaughter plays in certain religious traditions and ensure that religiously significant meats—such as kosher, halal, and Amish meats—are not impacted by the rule's prohibition on discrimination on the basis of the producer's religion. According to AMS subject matter experts, halal slaughterers, for example, express a legitimate, religiously grounded preference for livestock and poultry raised by operators of faith, *e.g.,* the Muslim or the Amish Christian group, that maintain particular animal husbandry practices. In adopting its prohibition on prejudice on the basis of religion, AMS is principally focused on access to the broad livestock markets for persons where religion has no legitimate business purpose. In contrast, where religion is relevant to the livestock and meat itself, AMS is not seeking to disturb the religiously based determinations in what is a relatively discrete market segment. Therefore, when administering the Act, AMS must allow discriminatory conduct directed toward fulfilling religious commitments surrounding livestock care and meat production.

To ensure clarity in its application, this rule respects longstanding jurisprudence surrounding Tribal sovereignty and the political relationship that a Tribe has with its members that secures the right for Tribal entities to preference Tribal members. To ensure that it is not read in contradiction with existing jurisprudence, the rule explicitly specifies that Tribal governments can engage in practices related to livestock, poultry, and meats with respect to non-Tribal entities or non-Tribal descendants. The prohibition on discrimination on the basis of race or color would be read to protect a person from discrimination for being of Native American descent, but not on preferential treatment given to Tribal members based on their political classification. This matter was specifically raised by, and is responsive to, Tribal governments during the Tribal consultation that AMS conducted and is described below under ''VII.C.—Executive Order 13175—Consultation and Coordination with Indian Tribal Governments.''

AMS recognizes that this rulemaking cannot foresee the range of unique or extenuating circumstances that may present in agricultural markets. Commenters stated that rapidly changing livestock and poultry markets may require an exception to the prohibition against undue prejudice or disadvantage on a protected basis. However, AMS did not identify, from the comments or based on its

experience, any other specific circumstances in the livestock and poultry industries where a prejudice against a producer on a prohibited basis was justified under the Act. To the extent that unforeseen circumstances could arise that would justify creating the need to allow for additional exceptions to this rule, AMS believes that those circumstances are likely to be rare and tailored to narrow circumstances. Accordingly, AMS believes that prosecutorial discretion will provide it with adequate flexibility to offer relief on a case-by-case basis. Of course, if following implementation of this rule it becomes evident that additional exceptions should exist in regulation, AMS may amend this regulation through the ordinary rulemaking process.

D. Retaliation Provisions

AMS proposed in § 201.304(b)(1) to prohibit retaliation against a covered producer that occurs because of the covered producer's participation in protected activities ''to the extent that these activities are not otherwise prohibited by Federal or state law, including antitrust laws.'' In the final rule, AMS modified the language of this provision to move the exception for Federal or State law, including antitrust laws, to paragraph (b)(2) and to add Tribal law to the types of law identified in this exception. AMS is adding this language to make explicit the applicability of Tribal law in this circumstance. Additionally, AMS changed ''because of'' to ''based upon'' both in response to comments and to align with its approach in § 201.304(a) and embodied in § 201.304(c). AMS proposed ''based upon'' in § 201.304(a) and ''by employing'' in § 201.304(c) to capture actions where the prohibited bases form a material part of the action—discrimination or prejudice, or as part of the deceptive practice. Section 201.304(b) is designed to achieve the same goal. AMS also received comments recommending broad protections for covered producers from retaliatory actions, including where the retaliation was a part of the decision to take an adverse action. AMS further underscores that ''based upon the covered producer's participation in an activity . . .'' covers threats that would reasonably dissuade or chill a covered producer from participating in the activities.

Under proposed § 201.304(b)(2)(i), AMS proposed to establish as a protected activity a producer's communication with a government agency on matters related to livestock, meats, or live poultry or petitions for redress of grievances before a court, legislature, or government agency. Commenters requested that AMS clarify that this protection covers communication with any sector or level of government, including State governments. AMS intends for this regulation to include protections for communications with any level of government, including any government committee or official. In this final rule, AMS is aligning the use of the terms ''court, legislature, or government agency'' and simplifying the language to say, ''government entity or official.'' This change ensures that protected communications may occur with any of the three branches of government, any level of government, and with individual government officials, including committees and members of a legislature.

AMS requested public comment on whether the final rule should protect producers who choose not to participate in protected activities. In response to public comment supporting this proposal, AMS has revised § 201.304(b)(2)(ii) to protect a producer's right to refuse a regulated entity's request to engage in communication with a government entity or official that is not required by law, and § 201.304(b)(2)(iii) to protect a producer's right to form or join, or to refuse to form or join, a producer or grower association or organization. Proposed § 201.304(b)(2)(ii), which protected a producer's assertion of any of the rights granted under the Act or this part, or assertion of contract rights, is renumbered as paragraph (b)(2)(vii) in the final rule.

AMS proposed in § 201.304(b)(2)(v) to protect producer communication or negotiation with a regulated entity for the purpose of exploring a business relationship. In response to public comment, AMS added in the final rule protection for communicating; negotiating; or contracting with a regulated entity, another covered producer, or with a commercial entity or consultant; for the purposes of exploring or entering into a business relationship. Commenters asserted that, as proposed, the protected activity was ''unreasonably narrow'' and that expanding this protection would ''help ensure that covered producers may *explore* all their business opportunities.'' [98] The Act is intended to ensure an inclusive market to protect and promote the ability for covered producers to compete.[99] Such competition may also take the form of exploring or entering into opportunities for enhanced price discovery through market intermediaries, such as listing cattle for competitive bidding on a publicly transparent exchange or selling at an auction barn or through a cooperative or other commercial entity that facilitates the marketing of livestock by the covered producer. The provision covers both the ability to negotiate or contract with the commercial entity or consultant serving as an intermediary or other facilitating the marketing or platform for marketing, such as the exchange or auction barn; and also the ability to negotiate or contract with other packers during the exchange or auction process. This is protected because both elements may be necessary parts of securing those opportunities to engage in price discovery and enhance the choice and competitive opportunities for covered producers to earn the full market value of their goods and services. The provision also covers consideration of alternative uses for farm property. As with all protected activities under this final rule, the regulated entity may not present an obstacle to engaging in these activities, whether written in a contract, verbally asserted, or otherwise, as those are impermissible under the Act.

Under proposed § 201.304(b)(3), AMS identified types of prohibited retaliatory conduct. Commenters expressed concern regarding the lack of clarity of these proposed prohibitions, with some saying the prohibitions were too broad, some arguing that the rule should provide even more flexibility, and some supporting the introduction of a ''catch-all clause'' to provide additional protection against retaliatory behavior. The final rule adds language to paragraph (b)(3)(ii) to prohibit performing under or enforcing a contract differently than with *similarly situated producers* [emphasis added]. This language, ''similarly situated,'' was commonly used by commenters and AMS in the proposed rule when discussing producer groups. The addition of ''similarly situated'' language provides greater specificity regarding the scope of the regulation by providing more context for a comparison of what differential

[98] ''Comment on AMS–FTPP–21–0045: Inclusive Competition and Market Integrity Under the Packers and Stockyards Act,'' available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0423.*

[99] See, *e.g.,* U.S. Department of Justice, ''Justice Department Files Lawsuit and Proposed Consent Decree to Prohibit Koch Foods from Imposing Unfair and Anticompetitive Termination Penalties in Contracts with Chicken Growers,'' Nov. 9, 2023, available at *https://www.justice.gov/opa/pr/justice-department-files-lawsuit-and-proposed-consent-decree-prohibit-koch-foods-imposing.*

performance or enforcement would look like.

The final rule also revises the provision prohibiting a regulated entity from refusing to deal with a covered producer by adding the language, ''on terms generally or ordinarily offered to similarly situated covered producers'' (paragraph (b)(3)(iv) in the final rule). In response to comments, AMS agrees that the rule as proposed provided too great a latitude for a regulated entity to engage in retaliation because a regulated entity could, for example, satisfy the proposed rule by simply offering highly unfavorable terms to the covered producer. AMS believes that this revision provides broader coverage regarding the most common circumstances that producers may encounter in their business dealings in which regulated entities may attempt to exact retaliation. It would also cover circumstances where the ''similarly situated producer'' was the covered producer's own prior status quo circumstance with the regulated entity before the covered producer engaged in the protected activity. AMS is also aligning refusal to deal under paragraph (a)(2)(ii) to address the similar risk of evasion.

Similarly, commenters requested that AMS add a regulation regarding contract modification, or contract renewal. AMS has amended proposed § 201.304(b)(3) to add a new paragraph (b)(3)(iii) to clarify that requiring a contract modification or a renewal on terms less favorable than for similarly situated producers is covered.[100] This provision covers any adverse change to the covered producer's contract terms if they are done in retaliation to a producer's engaging in protected activities. Additionally, in response to comments requesting AMS clarify that prohibited adverse actions ''includes but is not limited to'' the list in proposed § 201.304(b)(3), AMS has added a new paragraph (b)(3)(vi) to prohibit ''any other action that a reasonable covered producer would find materially adverse.'' AMS designed this rule to protect producers broadly from adverse actions based upon the rule's prohibitions. The regulatory text of the proposed rule set forth an exemplary list, specifically denoting that ''retaliation includes the following actions'' (paragraph (b)(2). Several public commenters wanted more producer protections, such as discriminatory conduct against producers by regulated entities through means outside of contractual devices. AMS agrees that adverse, retaliatory treatment of producers by regulated entities can occur through a wide range of means, including outside the confines of contractual devices, or through contractual means that are not easily delineated in a specific list. Such conduct could, for example, include interference by a regulated entity into regulatory matters of significant material importance to producers. Based on AMS's regulatory experience, regulated entities may interfere in covered producers' water rights, which are exemplary of harms that would be considered retaliation even if they occur outside the confines of contractual relationships. Or, conduct could include retaliation during the contracting process for protected activities that occurred prior to the covered producer's attempt to form a business relationship with the regulated entity. Such examples might not be clearly covered under §§ 201.304(b)(3)(i) through (v) of the proposed rule's protections relating to contracts but were covered within the scope of the proposed rule's intent around broad-ranging adverse actions that harm producers. AMS also intends the list of retaliatory activities to be broad enough to capture the fullest range of materially adverse harms encompassed under unjust discrimination and undue prejudice—including in comparison to either their prior circumstances or to similarly situated producers—and threats of such harms that are designed to deter or punish producers from participating in the activities protected by this final rule. Therefore, § 201.304 (b)(3)(vi) has been added to the final rule to cover other types of adverse treatment. This provision provides a broad and flexible approach to these prohibitions and allows for ''material'' to be determined by the facts and circumstances of each case.

In making these changes, the final rule provides a greater degree of specificity regarding the type of conduct the rule prohibits. AMS is not, however, providing the degree of specificity requested by commenters regarding unfavorable contract terms because it is impractical to name every action a malicious actor could use to retaliate against a producer, and providing this level of detail is not necessary to enforce the rule.

E. Technical Changes

AMS made editorial changes to the text of several proposed regulations to improve clarity and readability. For instance, in the definition of *livestock producer,* AMS revised the proposed definition by removing multiple prepositions, so that the definition in the final rule reads more simply: from ''*Livestock producer* means any person engaged in the raising and caring for livestock by the producer or another person, whether the livestock is owned by the producer or by another person, but not an employee of the owner of the livestock'' to ''*Livestock producer* means any person, except an employee of the livestock owner, engaged in the raising of and caring for livestock.'' Additionally, AMS revised the syntax of several proposed regulations. For example, in § 201.304(b)(3)(i), which lists prohibited retaliatory actions, AMS revised the phrasing of the prohibition from ''Termination of contracts or non-renewal of contracts'' to ''Terminating or not renewing a contract'' to place emphasis on the action being prohibited rather than the subject of that action.

AMS also made several non-substantive clarifying changes to the wording of prohibited contractual deceptive practices in paragraphs (b) and (c) of § 201.306—Deceptive practices. These changes are identical under *contract formation, performance, and termination* and include the removal of the phrase ''pretext'' and ''fact'' and the inclusion of the term ''information'' in place of ''fact.'' The term ''pretext'' was removed because it is not needed to accomplish the objectives of § 201.306. The conduct this rule aims to prohibit is more directly defined through use of the following language: ''*false or misleading statement or representation, or omission of material information.*'' By changing the term ''fact'' to ''information'' certain conduct that may not be considered or defined as ''factual'' under the Act, yet is still deceptive, will be covered.

Lastly, AMS made a technical change to the table of contents for subpart O. To avoid confusion, AMS is including §§ 201.303 and 201.305 in the table of contents as reserved sections to indicate the gaps between §§ 201.302, 304, and 306 are deliberate and that sections have not been inadvertently omitted.

VI. Provisions of the Final Rule

Under the authority of the Act, this rule adds a new subpart O to AMS's regulations in 9 CFR 201, titled ''Competition and Market Integrity,'' and consisting of §§ 201.300 through 201.390. This section summarizes the substantive provisions of the new subpart.

A. Definitions (§ 201.302)

Section 201.302 defines three terms for subpart O: *covered producer, livestock producer,* and *regulated entity.*

[100] Proposed paragraphs (b)(3)(iii) and (iv) are accordingly renumbered as paragraphs (b)(3)(iv) and (v) in the final rule.

A *covered producer* is defined as a livestock producer (as defined in § 201.302) or swine production contract grower or poultry grower as defined in section 2(a) of the P&S Act (7 U.S.C. 182(8), (14)). Under section 2(a) of the Act, swine production contract grower means any person engaged in the business of raising and caring for swine in accordance with the instructions of another person. A live poultry grower is defined under section 2(a) of the Act as any person engaged in the business of raising and caring for live poultry for slaughter by another, whether the poultry is owned by such person or by another, but not an employee of the owner of such poultry. AMS is adopting this definition to facilitate a focus in this rule on protecting livestock producers (and other parties included in the definition of covered producer) because the harms of discrimination, retaliation, and deception that are addressed in this rule are directed toward and experienced by those persons. Therefore, even though the Act does not contain a definition for livestock producers, AMS has included livestock producers under the definition of *covered producer;* and provided a definition for the term *livestock producer* in this section.

Livestock producer is defined for the purposes of subpart O as being any person, except an employee of the livestock owner, engaged in the raising of and caring for livestock. AMS aligned its definition of the term *livestock producer* with phrasing used in the Act for the terms poultry grower and swine production contract grower. In response to comment to the proposed rule, AMS revised its definition by removing unnecessary and potentially confusing phrasing. Employees are specifically excluded as they typically lack direct financial interest in the livestock themselves.

AMS defines *regulated entity* as a swine contractor or live poultry dealer as defined in section 2(a) of the Act (7 U.S.C. 182(8)) or a packer as defined in section 201 of the Act (7 U.S.C. 191). A swine contractor is defined in the Act as any person engaged in the business of obtaining swine under a swine production contract for the purpose of slaughtering the swine or selling the swine for slaughter, if (a) the swine is obtained by the person in commerce or (b) the swine (including products from the swine) obtained by the person is sold or shipped in commerce. Live poultry dealers, the vast majority of whom are organized in a vertical structure with common ownership interest in inputs, often referred to as poultry integrators, are defined in the Act as any person engaged in the business of obtaining live poultry by purchase or under a poultry growing arrangement for the purpose of either slaughtering it or selling it for slaughter by another, if poultry is obtained by such person in commerce, or if poultry obtained by such person is sold or shipped in commerce, or if poultry products from poultry obtained by such person are sold or shipped in commerce. A packer is defined in the Act as any person engaged in the business (a) of buying livestock in commerce for purposes of slaughter; or (b) of manufacturing or preparing meats or meat food products for sale or shipment in commerce; or (c) of marketing meats, meat food products, or livestock products in an unmanufactured form acting as a wholesale broker, dealer, or distributor in commerce.

B. Undue Prejudice and Unjust Discrimination (§ 201.304(a))

Section 201.304(a) addresses the unique and often difficult to prove discriminatory conduct that has long existed in the agricultural sector by prohibiting specific bases of prejudicial action. Paragraph (a) also lists prohibited actions taken on a prejudicial basis and provides clarification on the types of actions that do not constitute prohibited action taken on a prejudicial basis. In doing so, AMS is clarifying the application of the Act, better empowering producers to protect themselves, and encouraging companies to adopt more robust compliance practices to snuff out conduct prohibited by the Act in its incipiency, before it can distort markets in the aggregate. In particular, this rule addresses the longstanding and often difficult to counter forms of exclusion that have plagued the agricultural sector for decades. AMS intends for this rule to support positive trends toward inclusivity in the marketplace. Prejudices and disadvantages based upon the producer's protected characteristics or status as a producers' cooperative have no place in today's modern agricultural markets.

The Act, through section 202(a) and (b), broadly prohibits certain practices or devices, including undue or unreasonable prejudices and disadvantages and unjust discrimination. Section 202(a) and (b) of the Act identifies several prohibited actions with respect to livestock, meats, meat food products, or livestock products in unmanufactured form, or for any live poultry dealer with respect to live poultry. In this rule, AMS is prohibiting specific undue and unreasonable prejudices and disadvantages, and unjust discrimination against any covered producer on the basis of certain categories of characteristics or attributes broadly and firmly established as unjust in a modern economy. This regulatory action implements Congress's intent, expressed through the Act, to stop unjust discrimination and undue prejudice by packers and live poultry dealers against livestock producers and poultry growers.

In enacting the Act, Congress cast a wide net to capture all acts of unjust discrimination and undue or unreasonable prejudice against any particular person. There is no indication that Congress intended to exempt any discriminatory conduct taken by regulated entities against producers covered under the Act.[101] The Act's prohibition of unjustly discriminatory or unreasonably prejudicial actions against a particular person was not a new statutory concept, as the Interstate Commerce Act of 1887 (or ICA) also banned unreasonable prejudices and unjust discriminatory practices well before the enactment of the Act. While the ICA does not define the scope of the Act, the comparison is nevertheless useful, especially with respect to the structure and design of provisions governing undue prejudices. A comparison is provided in Table 4 below.

In *Mitchell* v. *United States,*[102] the Supreme Court of the United States held that the ICA prohibited discrimination based on race; such discrimination was ''essentially unjust.'' The Court held that ''it is apparent from the legislative history of the ICA that not only was the evil of discrimination the principal thing aimed at, but that there is no basis for the contention that Congress intended to exempt any discriminatory action or practice of interstate carriers affecting interstate commerce which it had authority to reach.'' [103] Further, the Court isolated a section of the ICA and noted that, ''Paragraph 1 of Section 3 of the Act says explicitly that it shall be unlawful for any common carrier subject to the Act 'to subject *any particular person to any undue or unreasonable prejudice or disadvantage* in any respect whatsoever.' '' [104] The Court found that unreasonable prejudice against an individual based on race was a violation and concluded that, ''the Interstate Commerce Act expressly

[101] *See* 7 U.S.C. 193. *C.f. Mitchell* v. *United States,* 313 U.S. 80, 94 (1941).

[102] 313 U.S. at 94.

[103] *Id.* at 94.

[104] *Id.* at 95 (emphasis added).

extends its prohibitions to the subjecting of 'any particular person' to unreasonable discriminations.'' [105]

The Act contains similar, but broader, language than sec. 3 of the ICA. Section 202 of the Act reads, ''It shall be unlawful for any packer or swine contractor with respect to livestock, meats, meat food products, or livestock products in unmanufactured form, or for any live poultry dealer with respect to live poultry, to: (a) Engage in or use any unfair, unjustly discriminatory, or deceptive practice or device; or (b) Make or give any undue or unreasonable preference or *advantage to any particular person* or locality in any respect, *or subject any particular person* or locality to any *undue or unreasonable prejudice or disadvantage* in any respect . . .'' [emphasis added]. Table 4 illustrates where the text between the two acts is similar, and also how the Act is broader.[106]

Table 4: Comparison of the Interstate Commerce Act and the Packers & Stockyards Act[107]

Interstate Commerce Act (1887 text), Section 3	Act, Section 202 (7 U.S.C.192), Unlawful practices enumerated
That it shall be unlawful for any common carrier subject to the provisions of this act to make or **give any undue or unreasonable preference or advantage to *any particular person***, company, firm, corporation, or locality, or any particular description of traffic, in any respect whatsoever,	It shall be unlawful for any packer or swine contractor with respect to livestock, meats, meat food products, or livestock products in unmanufactured form, or for any live poultry dealer with respect to live poultry, to:
or to subject *any particular person,* company, firm, corporation, or locality, or any particular description of traffic, **to any undue or unreasonable prejudice or disadvantage in any respect whatsoever.**	(a) Engage in or use any unfair, unjustly **discriminatory**, or deceptive practice or device; or
Every common carrier subject to the provisions of this act... **shall not discriminate in their rates and charges between such connecting lines[.]** (emphasis added)	(b) Make or give any undue or unreasonable preference or advantage to any particular person or locality in any respect, or subject ***any particular person*** or locality to any **undue or unreasonable prejudice or disadvantage in any respect**; (emphasis added)

As shown in Table 4, unlike the ICA, the Act in secs. 202(a) and (b) prohibits undue or unreasonable prejudices or disadvantages *as well as* deception *or* unjust discrimination (without limitation to discrimination in rates and charges in particular). In this rulemaking, AMS applies the language from sec. 202 to prohibit acts of unreasonable prejudice and to prevent unjust discrimination including, but not limited to, the race discrimination that the Court found to be violative of the ICA in *Mitchell.*

This rule sets forth specific prohibitions on prejudicial or discriminatory acts or practices against individuals that are sufficient to demonstrate violation of the Act without the need to further establish broad-based, market-wide prejudicial or discriminatory outcomes or harms. The prohibitions in this rule on regulated entities adversely treating individual producers address the types of harms the Act is intended to prevent. AMS finds that adverse acts on these bases are essentially unjust and unduly prejudicial, and actionable at the individual level. Moreover, AMS

[105] *Id.* at 97.

[106] For more on the relationship between the Interstate Commerce Act and the Act in this area, *see* Michael Kades, ''Protecting Livestock Producers and Chicken Growers,'' Washington Center for Equitable Growth, at 66 (May 2022) discussing *Wheeler* v. *Pilgrim's Pride Corp.,* 591 F.3d 355, 368–369 (5th Cir 2009) (en banc) (J. Jones concurring): ''In all the cases discussed by the concurrence dealing with both terms [under the ICA], the defendant faced charges that it treated customers differently. According to the court, 'railway companies are only bound to give the same terms to all persons alike under the same conditions.' If the conditions are different, then different treatment is merited. Further, 'competition between rival routes is one of the matters which may lawfully be considered in making rates.' Differential treatment driven by competitive forces is not a violation. Acknowledging that competition can justify differential treatment of customers is different than requiring the plaintiff to prove anticompetitive harm to establish a violation.''

[107] Bolded text highlights where the ICC and Act use similar language. Italicized text identifies areas where the language of both statutes is the same.

believes that preventing broad-based exclusion, and therefore promoting competitive markets, is most effectively enforced at the individual producer level when the conduct is in its incipiency.[108] To further allow for effective enforcement of the statute, AMS is also including a recordkeeping requirement to support evaluation of regulated entity compliance.

In determining the bases for protection against discrimination under the Act, AMS drew insight initially from the Statement of General Policy Under the Packers and Stockyards Act published by the Secretary in 1968 (Statement of General Policy) (9 CFR 203.12(a)), which states that the Act provides that all stockyard services furnished at a stockyard ''shall be reasonable and nondiscriminatory and stockyard services which are furnished shall not be refused on any basis that is unreasonable or unjustly discriminatory.'' [109] Additionally, AMS interprets the Act consistently with the regulations governing USDA-conducted programs; ECOA, which is enforced in part by AMS under the Act; a series of statutes identifying producers that Congress has determined face special disadvantages, are underserved, or are otherwise more vulnerable to prejudices; and the Agricultural Fair Practices Act (AFPA) of 1967.

The Statement of General Policy reflects the current USDA policy on the enforcement of the Act. The Statement of General Policy provides in part that it is a violation of secs. 304, 307, and 312(a) of the Act for a stockyard owner or market agency to discriminate, in the furnishing of stockyard services or facilities or in establishing rules or regulations at the stockyard, because of *race, religion, color, or national origin* of those persons using the stockyard services or facilities. Such services and facilities include, but are not limited to, the restaurant, restrooms, drinking fountains, lounge accommodations, those furnished for the selling, weighing, or other handling of the livestock, and facilities for observing such services.

While this part of the Statement of General Policy applies to violations of secs. 304, 307, and 312(a) of the Act (related to the provision of services and facilities at stockyards on an unreasonable and discriminatory basis), almost identical prohibitive language is used in sec. 202 of the Act. Section 202 pertains to packers, swine contractors, and live poultry dealers. Section 202(a) of the Act prohibits any unjustly discriminatory practice or device with respect to livestock, meats, meat food products or livestock products in manufactured form, or live poultry.

AMS also considered USDA's general regulatory prohibition against discrimination in USDA programs, which governs how USDA provides services to producers. In 1964, USDA prohibited discrimination on the basis of race, color, and national origin in its Federally conducted activities by adopting Title VI principles.[110] USDA then expanded the protected bases for its conducted programs to include religion, sex, age, marital status, familial status, sexual orientation, disability, and whether any portion of a person's income is derived from public assistance programs.[111] Most recently updated in 2014, the general regulatory prohibition offers a more current interpretation of antidiscrimination standards.[112] The 2014 rule aimed to ''strengthen USDA's ability to ensure that all USDA customers receive fair and consistent treatment, and align the regulations with USDA's civil rights goals.'' [113] The relevant provision provides that no agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or gender identity, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA. In that rulemaking, USDA identified areas where discrimination against a producer is an unacceptable denial of access to USDA's services. This prior rulemaking provides a helpful reference to what constitutes unjust discrimination under the Packers and Stockyards Act.

AMS interprets the Act in light of legislative mandates that emerged over the last 30 years directing USDA to make extra efforts to ensure that members of the aforementioned groups have equal access to USDA's services and agricultural markets generally.[114] Congress adopted numerous statutes seeking to remedy market exclusion on the basis of prejudices across a wide range of areas, including: 7 U.S.C. 8711 (base acres); 7 U.S.C. 2003 (target participation rates); 7 U.S.C. 7333 (Administration and operation of noninsured crop assistance program); 7 U.S.C. 1932 (Assistance for rural entities); 16 U.S.C. 2202a, 3801, 3835, 3839aa–2, 3841, and 3844 (conservation); 7 U.S.C. 8111 (Biomass Crop Assistance Program); 7 U.S.C. 1508 (Federal crop insurance, covering underserved producers defined as new, beginning, and socially disadvantaged farmers or ranchers and including members of an Indian Tribe); and 16 U.S.C. 3871e(d) (conservation, covering historically underserved producers defined as being veteran, socially disadvantaged, and limited-resource farmers and ranchers). In 25 U.S.C. 4301(a) and elsewhere, Congress has clearly expressed its intent for the United States Government to encourage and foster Tribal commerce and economic development.[115]

The definitions and coverage in these statutes vary to some extent. Some focus principally on members of groups that have experienced racial or ethnic prejudices, while others address gender prejudices. Overall, these statutes and Congressional deliberations provide useful reference for USDA to most effectively carry out the Act, which outlaws undue prejudice against any person in any respect. For example, in the congressional hearings preceding the Act's passage, opposing members argued against the Act because producers were already protected by the ICA, which guaranteed ''equal rights on the railroads to every man, woman and

[108] ''[T]he purpose of the Act is to halt unfair trade practices in their incipiency, before harm has been suffered.'' *See Farrow* v. *U.S. Dep't of Agr.,* 760 F.2d 211, 215 (8th Cir. 1985) (citing *De Jong Packing Co.* v. *U.S. Dep't of Agric.,* 618 F.2d 1329, 1336–37 (9th Cir. 1980); *Swift & Co.* v. *United States,* 393 F.2d 247, 252 (7th Cir. 1968); *Armour and Company* v. *United States,* 402 F.2d 712, 723 n. 12 (7th Cir.1968).

[109] Statement of General Policy Under the Packers and Stockyards Act. U.S. Department of Agriculture: Washington, DC, 1968.

[110] *https://www.federalregister.gov/documents/2014/07/16/2014-16325/nondiscrimination-in-programs-or-activities-conducted-by-the-united-states-department-of-agriculture* (See 29 FR 16966, creating 7 CFR part 15, subpart b, referring to nondiscrimination in direct USDA programs and activities, now found at 7 CFR part 15d). (assessed 01–30–2024)

[111] *https://www.federalregister.gov/documents/2014/07/16/2014-16325/nondiscrimination-in-programs-or-activities-conducted-by-the-united-states-department-of-agriculture* (assessed 01/30/2024)

[112] 7 CFR 15d.3; U.S. Department of Agriculture, ''Nondiscrimination in Programs or Activities Conducted by the United States Department of Agriculture,'' 79 FR 41406, July 16, 2014, available at *https://www.federalregister.gov/documents/2014/07/16/2014-16325/nondiscrimination-in-programs-or-activities-conducted-by-the-united-states-department-of-agriculture* (last accessed 8/9/2022).

[113] USDA. 2014. 7 CFR part 15d RIN 0503–AA52 Nondiscrimination in Programs or Activities Conducted by the United States Department of Agriculture, p. 41407. 2014–16325.pdf (*govinfo.gov*) (assessed 02/01/2024).

[114] For background, *see* Congressional Research Service, *Defining a Socially Disadvantaged Farmer or Rancher (SDFR): In Brief* (March 19, 2021), available at *https://crsreports.congress.gov/product/pdf/R/R46727/6.*

[115] See, *e.g.,* Native American Business Development Act, 25 U.S.C. 4301(a).

child,'' and the ''enforcement of the antitrust act . . . give[s] every man a fair show.'' [116] Most recently, Congress provided partial compensation for producers who suffered discrimination in USDA's programs, which USDA implemented on a set of protected bases similar to that in this final regulation.[117]

Additionally, in crafting the final rule, AMS was informed by the provisions of two additional laws that fall under the enforcement of USDA with respect to livestock and poultry. The first is ECOA. ECOA prohibits a creditor from discriminating in the provision of credit on the basis of race, color, religion, national origin, sex (which includes sexual orientation and gender identity), marital status, or age, because the applicant's income derives all or in part from a public assistance program, or because the applicant has in good faith exercised any right under ECOA.[118] The Secretary enforces ECOA under the Act, with respect to activities under the jurisdiction of the Act.[119]

Secondly, AFPA protects producers from retaliation by certain market intermediaries, defined as handlers, for being members of a cooperative or seeking to form a cooperative.[120] The Secretary has delegated enforcement of the AFPA to AMS, which implements the law through the Packers and Stockyards Division. Congress has long protected the rights of agricultural cooperatives, acknowledging their important role in helping farmers meet the economic demands of the market. One year after the passage of the Act, Congress passed the Capper-Volstead Act (Pub. L. 67–146), which permits producer cooperatives to collectively process, prepare for market, handle, and market their products. In a decision related to an antitrust action against a nonprofit cooperative association whose members were involved in production and marketing of broiler chickens, the Supreme Court noted that farmers faced special challenges in the agricultural market and, therefore, cooperatives are afforded legal protections in helping them address those challenges.[121]

AFPA provides enhanced protections to those seeking to form a cooperative. In particular, that statute prevents handlers from performing certain types of pricing and contract discrimination, coercion, and other practices that undermine cooperatives. As noted previously, the Act intended to improve the agricultural market and includes associations in the definition of ''person'' when referred to in the Act. The Act affords cooperative associations the same protections against discrimination as are afforded to all other covered producers.[122] Thus, protections for cooperatives against discrimination were contemplated at the time of the Act's passage.[123]

In interpreting the Act in light of the aforementioned policy direction, AMS has sought to stamp out market exclusion on prohibited bases. This final rule establishes a prohibition of undue prejudice or unjust discrimination against covered producers on the bases of race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, or age; or because of the covered producer's status as a cooperative. Transitioning from the proposed rule's use of the more flexible ''market vulnerable individual'' to the more specific list of delineated terms, the final rule interprets the Act consistent with the antidiscrimination mandates in other related statutes, including the ECOA, which is already enforced by AMS for markets subject to the Act,[124] and the AFPA. AMS also references the Equal Employment Opportunity Commission (EEOC) definitions (described below) for clarification regarding which characteristics a producer must possess to be considered a member of one or more protected classes. It is appropriate for the Secretary to consider these other authorities in effectuating the purposes of the Act as they effect a similar purpose to this final rule.[125]

The EEOC has described racial discrimination as discrimination based on an ''immutable characteristic associated with race, such as skin color, hair texture, or certain facial features.'' Although race and color may appear indistinguishable, they are not. According to the EEOC, ''color discrimination occurs when a person is discriminated against based on the lightness, darkness, or other color characteristic of the person.'' [126] Race discrimination involves treating an individual differently because of his or her race. National origin as a protected class is defined as disparate treatment because an individual is ''from a particular country or part of the world, because of ethnicity or accent, or because they appear to be of a certain ethnic background (even if they are not).'' [127] Ethnicity is covered under national origin.[128] Religion as a protected basis is defined as discrimination based upon a person's religious beliefs. EEOC reports that the law protects people in recognized ''organized religions,'' but also those ''who have sincerely held religious, ethical or moral beliefs.'' [129] Sex as a protected basis includes discrimination based upon a person's status as pregnant, one's sexual orientation, and one's gender identity.[130] The EEOC

[116] *See e.g.,* 61 Cong. Rec. H1872 (1921).

[117] Section 22007 of the Inflation Reduction Act (Pub. L. 117–169). USDA implementation available at *https://22007apply.gov/*. This program covers discrimination based on different treatment an individual experienced because of race, color, or national origin/ethnicity (including status as a member of an Indian Tribe); sex, sexual orientation, or gender identity; religion; age; marital status; disability; reprisal/retaliation for prior civil rights activity.

[118] 15 U.S.C. 1691(a).

[119] 15 U.S.C. 1691c.

[120] 7 U.S.C. 2301 *et seq.*

[121] *Nat'l Broiler Mktg. Ass'n* v. *United States,* 436 U.S. 816, 825–26 (1978) (''Farmers were perceived to be in a particularly harsh economic position. They were subject to the vagaries of market conditions that plague agriculture generally, and they had no means individually of responding to those conditions. Often the farmer had little choice about who his buyer would be and when he would sell. A large portion of an entire year's labor devoted to the production of a crop could be lost if the farmer were forced to bring his harvest to market at an unfavorable time. Few farmers, however, so long as they could act only individually, had sufficient economic power to wait out an unfavorable situation. Farmers were seen as being caught in the hands of processors and distributors who, because of their position in the market and their relative economic strength, were able to take from the farmer a good share of whatever profits might be available from agricultural production. By allowing farmers to join together in cooperatives, Congress hoped to bolster their market strength and to improve their ability to weather adverse economic periods and to deal with processors and distributors.'').

[122] 7 U.S.C. 182(1).

[123] H.Rep. No. 85–1048, 1957.

[124] 15 U.S.C. 1691c(a)(5) (''(a) Enforcing Agencies. Subject to subtitle B of the Consumer Protection Financial Protection Act of 2010withthe requirements imposed under this subchapter shall be enforced under:. . . (5) The Packers and Stockyards Act, 1921 [7 U.S.C. 181 *et seq.*] (except as provided in section 406 of that Act [7 U.S.C. 226, 227]), by the Secretary of Agriculture with respect to any activities subject to that Act.'')

[125] Michael Kades, ''Protecting Livestock Producers and Chicken Growers,'' *Washington Center for Equitable Growth* (May 5, 2022), available at *https://equitablegrowth.org/research-paper/protecting-livestock-producers-and-chicken-growers/*.

[126] U.S. Equal Employment Opportunity Commission (EEOC), No date, Facts about Race/Color Discrimination, available at *https://www.eeoc.gov/fact-sheet/facts-about-racecolor-discrimination.*

[127] U.S. Equal Employment Opportunity Commission (EEOC), National Origin Discrimination, available at *https://www.eeoc.gov/national-origin-discrimination.*

[128] Ibid.

[129] U.S, Equal Employment Opportunity Commission (EEOC), Religious Discrimination, available at *https://www.eeoc.gov/religious-discrimination.*

[130] U.S, Equal Employment Opportunity Commission (EEOC), Sex, available at *https://www.eeoc.gov/youth/sex-discrimination#:~:text=EEOC%20enforces%20two%20laws%20that,sexual%20orientation%2C%20and%20gender%20identity.*

defines disability as follows: ''Has a physical or mental condition that substantially limits a major life activity;'' a ''history of disability,'' and ''is subject to an adverse employment action because of a physical or mental impairment the individual actually has or is perceived to have, except if it is transitory (lasting or expected to last six months or less) *and* minor.'' [131]

ECOA defines marital status as the ''existence, absence, or likelihood of a marital relationship between the parties,'' and so marital discrimination would be upon those bases.[132] Age discrimination is defined as discrimination against those individuals 40 and older on the basis of their age.[133] Cooperatives are described as ''producer and user-owned businesses that are controlled by, and operate for the benefit of, their members, rather than outside investors.'' [134] As explained above, in formulating this rule, AMS principally drew on its expertise and comments gathered from market participants about how undue discrimination manifests in markets, and considered the relevant references that concern this type of discrimination. These include the above referenced EEOC, ECOA, and AFPA-related approaches because these approaches: first, align with the intent of the Act to prohibit all instances of unjust discrimination and undue prejudice; second, effectuate the purposes of the final rule to clearly prohibit that discrimination; and third, promote more inclusive competition by protecting the individuals who participate in the market.

Because of the Act's broad applicability (as discussed in section III—''Authority''); the similar language used in secs. 202, 304, 305, and 312 of the Act; and the series of statutes outlining a range of prejudices identified as being deserving of public policy efforts to ensure full market access; AMS concludes that producers who have been subjected to discrimination, prejudice, disadvantage, or exclusion on the specific bases set forth in this final rule should be covered by the prohibitions against undue prejudice or disadvantage and unjust discrimination as enumerated by sec. 202 of the Act.

To stamp out unjustly discriminatory and unduly prejudicial conduct and support a more inclusive marketplace, AMS, in § 201.304, lays out the protected bases against which undue prejudices or disadvantages and unjust discrimination are prohibited, and then describes the specific conduct that, when initiated against a producer belonging to one of the protected bases, is prohibited. Paragraph (a)(1) prohibits a regulated entity from prejudicing, disadvantaging, inhibiting market access, or otherwise taking an adverse action against a covered producer on the basis of the covered producer's (i) race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, or age; or (ii) the covered producer's status as a cooperative. The sources of these bases are discussed above. Paragraph (a)(1)'s prohibition as ''based upon'' is intended to be broader than ''but for'' causation and so capture when the protected characteristics or status are a material, or non-trivial, element of the decision to take an adverse action against a covered producer. AMS expects that fact-finding tribunals will establish the necessary processes for proving these elements, with an eye toward the protections for covered producers and for open, inclusive markets that this rule is designed to provide.

Though this regulation prohibits prejudice or disadvantage against a covered producer on the basis of the specified statuses, AMS notes that regulated entities may decline to do business with covered producers for justified economic reasons. For example, a regulated entity may refuse to contract with a cooperative of covered producers when the contract would not be cost-effective for the entity, regardless of the cooperative status of the producers. In this hypothetical example, the regulated entity would not be unduly prejudicing cooperatives of covered producers based on their status as a cooperative. Instead, the regulated entity would have a nonprejudicial basis for its business decision.

Section 201.304(a)(2) describes the actions that prejudice, disadvantage, inhibit market access, or are otherwise adverse under paragraph (a)(1). These actions were chosen because they relate to fairness in contracting, which is a consistent concern among producers; and are actions that PSD has determined are a recurring problem in the industry, directly impacting producers' financial well-being. In response to the proposed rule, many commenters noted the financial repercussions of lack of fairness in contracting.[135] Under § 201.304(a)(2), regulated entities may not prejudice or disadvantage covered producers on the basis of a protected status by: (i) offering contract terms that are less favorable than those generally or ordinarily offered to similarly situated covered producers; (ii) refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers; (iii) performing under or enforcing a contract differently than with similarly situated covered producers; (iv) requiring a contract modification or renewal on terms less favorable than similarly situated covered producers; (v) terminating or not renewing a contract with a covered producer; and (vi) any other action that a reasonable producer would find materially adverse.

Paragraph (a)(2)(i) prohibits the offering of less favorable contract terms to covered producers on the basis of their status as members of a protected class. In the Agency's experience, offering less favorable contract terms than those generally or ordinarily offered to similarly situated covered producers is a means through which regulated entities can prejudice or disadvantage producers. For example, the Agency has received complaints that the bidding on livestock by regulated entities occurs at a less advantageous time for certain producers on the basis of the classes protected under this rule resulting in lower prices or less favorable delivery terms. Similarly, in the Agency's experience, poultry growers have complained about being offered less favorable growing terms on the basis of the classes protected under this rule. This rule does not prohibit ordinary contracting for different prices on the basis of differences in product

[131] U.S. Equal Employment Opportunity Commission (EEOC). No date. Disability Discrimination and Employment Decisions. Accessed at *https://www.eeoc.gov/disability-discrimination-and-employment-decisions* on November 15, 2023.

[132] Equal Credit Opportunity Act (ECOA). No date. Access at *https://www.fdic.gov/resources/supervision-and-examinations/consumer-compliance-examination-manual/documents/5/v-7-1.pdf.*

[133] U.S. Equal Employment Opportunity Commission (EEOC). No date. Age Discrimination. Accessed at *https://www.eeoc.gov/age-discrimination* on 10–04–2023.

[134] Co-ops: A Key Part of Rural America, *Co-ops: A Key Part of Rural America,* USDA, available at *https://www.usda.gov/topics/rural/co-ops-key-part-fabric-rural-america.* See also AFPA § 2301. Congressional findings and declaration of policy.

[135] *See e.g.,* ''Discrimination and retaliation mean big profits for companies at the farmer's expense. While meatpackers rake in record profits during the pandemic, farmers make less, and eaters are left paying more at the grocery store. Farmers who complain about their pay or the fairness of their contracts run the risk of losing their contracts, putting their homes and livelihoods at risk.'', available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0051;* see also, ''This rule is much needed so farmers can tell the truth about their contracts and so consumers can know what producers are actually doing to the earth, the animals, and the farmers.'', available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0298.*

quality, service, transportation cost, or delivery terms.

Paragraph (a)(2)(ii) prohibits regulated entities from refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers. This refers to situations in which a regulated entity makes no reasonable effort to deal, bid, or negotiate with a covered producer on the basis of the covered producer's status as a member of a protected class. Such refusal to deal has no connection with the service or quality of product offered, but rather is due, in material part, to the personal characteristics or status of the producer and restricts the producers' ability to obtain the fair market value of their products and services. In today's highly vertically integrated and concentrated markets, refusal to deal by one regulated entity will often leave a producer with very few, if any, parties to contract with, unduly inhibiting the competitive marketplace when performed on the bases prohibited by this final rule.

Paragraph (a)(2)(iii) prohibits regulated entities from performing under or enforcing a contract differently than with similarly situated producers. A violation of this regulation would occur when a regulated entity—based upon the covered producer's protected characteristics—inconsistently enforces its contracts as it would with similarly situated producers. For instance, a selective information disclosure would represent a selective performance of contract when a regulated entity withholds materially relevant information from one covered producer that the regulated entity generally or ordinarily provides to other covered producers. In these instances, information-deprived producers will have an incomplete picture of their business relationships with regulated entities, and therefore will operate at an unreasonable disadvantage relative to producers who receive the pertinent information. Similarly, the Agency has received complaints over the years with respect to differential performance under poultry growing arrangements, such as the delivery to affected growers of flocks that are sick or otherwise known to be likely to perform poorly owing to the age of the hens. Those sick or poor performing chicks are likely to result in lower performance for the grower in a poultry grower ranking system, which results in lower pay for the grower. While that may occur from time to time per natural cycles, a repeated or intentional delivery of underperforming flocks has been commonly reported by producers as a principal means of adversely affecting grower earnings. Similarly, a regulated entity withholding or delaying delivery of feed would result in lower performance and profit for a producer. Accordingly, AMS has incorporated differential contract performance to capture those contractual performance-based means to prejudice or disadvantage producers. By clarifying in its final rule that the Act prohibits such conduct, AMS seeks to better protect producers who suffer, or are at risk of suffering, this type of harm.

Paragraph(a)(2)(iv) prohibits a regulated entity from, on the basis of a covered producer's protected status, requiring a contract modification or renewal on terms less favorable than those for similarly situated covered producers. The Agency has determined, based on producer complaints, that regulated entities sometimes prejudice or disadvantage growers by reducing numbers of flocks delivered, changing types of birds raised, or otherwise changing contract terms that result in lower incomes for growers. Poultry producers commonly experience these types of contract modifications. Livestock producers also experience modifications, such as a change from a cash negotiated contract to a negotiated grid contract or other purchase type that may be adverse from the perspective of the producer depending on the facts and circumstances. Therefore, in the final rule, AMS seeks to clarify that unfavorable contract modification or renewal by a regulated entity, on the basis of a protected class, amounts to a violation under the Act. This rule, by itself does not prohibit renegotiations or failure to renew a contract on the basis of changes in the market. However, while this rule does not distinguish modification for other reasons, many contract terms under the Act are not subject to modification during performance of the contract *at all* because any contract modification that serves to delay or reduce full payment is an unfair practice under sec. 202(a) of the Act.

Paragraph (a)(2)(v) prohibits regulated entities from terminating or not renewing a contract with a covered producer on the basis of a covered producer's status as a protected class. Contract termination can have devastating consequences for producers that have invested substantial sums in infrastructure that only meets the requirements of a particular integrator.

Paragraph (a)(2)(vi) prohibits regulated entities from any other action that a reasonable covered producer would find materially adverse. This provision provides a broad and flexible approach to these prohibitions and allows for ''material'' to be determined by the facts and circumstances of each case where producers were harmed.

Finally, § 201.304(a)(3) delineates two exceptions to the prohibition on prejudicial or discriminatory conduct against covered producers on a protected basis. In one, the regulated entity is fulfilling a religious commitment relating to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry; in the other, a Federally recognized Tribe, including its wholly or majority-owned entities, corporations, or Tribal organizations, is performing Tribal governmental functions. As discussed in Section V—Changes from the Proposed Rule, these exceptions were added in response to commenters' request that some exceptions be provided to the prohibition on undue prejudice and unjust discrimination. To safeguard the free exercise of religion, AMS has provided an exception to allow discriminatory conduct necessary to fulfill religious commitments surrounding livestock care and meat production. To conform with longstanding jurisprudence surrounding Tribal sovereignty, AMS has provided an exception to allow Tribal entities to preference their own Tribal members in the purchase and sale of livestock.

C. Retaliation (§ 201.304(b))

Section 201.304(b) establishes protected activities for covered producers and prohibits regulated entities from engaging in retaliatory conduct based on those activities. As noted previously, sec. 202(a) of the Act prohibits unjust discrimination. This regulation is designed to protect the essential activities producers must engage in to bargain effectively and exercise their economic rights, and in doing so obtain the full value of their livestock or poultry products or services. As a result, retaliation against producers because they have engaged in protected activities is disparate treatment that the Act intended to prohibit.[136] Retaliatory conduct is a way for regulated entities to exploit their market power. Increased concentration has facilitated the exercise of market power through various contracting practices. Moreover, because producers

[136] *See e.g.,* 61 Cong. Rec. H1860 (1921): ''However, their [packers] very organization has given them a power for evil as well as good, and evil practices should always be condemned.'' and ''. . . the right thing to do is to devise a law which, while maintaining and getting the advantage for the people of all of the fine workings of these great organizations, at the same time control them in such a way as to destroy the abuses that are connected with their operation.''

have few processor choices in these markets, threats of retaliation and market exclusion take on heightened credibility.

AMS determined the protected activities to include in § 201.304(b)(2) based on commonly recorded complaints from the industry, case law, USDA/DOJ workshops, conversations with AMS personnel, and a recently voiced concern from Congress. AMS also identified these types of activities because of their potential to mitigate certain ways that market power is exercised. The retaliatory conduct prohibited by this regulation covers a broad range of circumstances that AMS has determined occur commonly in connection with livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. Free exercise of the protected activities facilitates a competitive and transparent market, ensuring producers can capture the full value of their livestock or growing services.

Section 201.304(b)(1) establishes that a regulated entity may not retaliate or otherwise take an adverse action against a covered producer based upon the covered producer's participation in protected activities. As described in Section V—Changes from the Proposed Rule,'' paragraph (b)(1)'s prohibition as ''based upon'' is intended to be broader than ''but for'' causation and so capture when the protected characteristics or status are a material, or non-trivial, element of the decision to take an adverse action against a covered producer. AMS expects that fact-finding tribunals will establish the necessary processes for proving these elements, with an eye toward the protections for covered producers and for open, inclusive markets that this rule is designed to provide.

Section 201.304(b)(2) lists the activities that are protected. Paragraph (b)(2) also provides a caveat that the protected activities must not otherwise be prohibited by Federal, Tribal, or State law, including antitrust laws. As outlined in the following paragraphs, these activities form an essential foundation for producers to receive the benefit of their bargained for exchange and the protections afforded under the Act itself. Acts of retaliation to chill or curtail these protected activities offer no competitive benefits to the market. Commenters to the proposed rule echoed these concerns.[137] The Act was designed to address market abuses and business practices that inhibit producers' ability to obtain the full value of their products and services.[138] Covered producers have complained to AMS over the years of having suffered retaliation or fearing retaliation for engaging in the conduct identified in this paragraph.

Specifically, paragraph (b)(2)(i) protects a covered producer's ability to communicate with a government entity or official or to petition a government entity or official for redress of grievances with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. A covered producer must be able to freely seek redress of grievances to ensure the protections afforded by the Act and its regulations have their intended effect. Government regulators must also have the ability to fully appreciate the views of market participants to ensure that the rules and regulations—and enforcement of those laws and regulations—are sufficiently responsive to market realities and divergent interests and business practices in the marketplace. Hindering the free flow of market information creates risks of market distortions and will impair the ability for those with less economic power to operate in the marketplace.

In paragraph (b)(2)(ii), AMS adds a new protection for a covered producer to refuse a regulated entity's request that the producer communicate with a government entity or official when that communication is not required by law. Just as covered producers have the right to communicate with government entities or officials to ensure their rights are protected, so too do they have the right to decide when and under what circumstances they engage in such communication. Based on its experience regulating the livestock sector, AMS is aware that regulated entities may coerce covered producers to contact the government on regulatory and policy matters and to espouse positions that the covered producers disagree with. AMS has received reports frequently in the past, and including within the last two years, of regulated entities pressuring producers to oppose regulations that the producers support, and covered producers reported similar concerns to AMS during earlier rulemaking initiatives as well. Indeed, regulated entities should not punish a covered producer for the producer's decision to talk to government agencies or not, regardless of the producer's reasons.

The lack of clarity around prohibitions on retaliation in agricultural markets—clarity which this rule aims to provide—impairs AMS's ability to investigate potential violations and effectively enforce the Act. Accordingly, AMS has added § 201.304(b)(2)(ii) to clarify that the rule protects a covered producer from retaliation if the covered producer decides not to engage in a communication with a government entity or official that is not required by law.

Paragraph (b)(2)(iii) protects a covered producer asserting the right to formor join—or to refuse to form or join—aproducer or grower association or organization, or cooperative, or the right to collectively process, prepare for market, handle, or market livestock or poultry. ''Asserting the right'' includes the preparatory steps necessary to form or join an association or cooperative. This provision protects two forms of producer interactions: cooperative and non-cooperative associations. The formulation ''to collectively process, prepare for market, handle, or market livestock or poultry'' refers to forming or joining a cooperative, tracking the language of the Capper Volstead Act.[139] Impeding the formation of cooperatives through retaliation harms competition as individual producers are deprived of the chance to mitigate market power abuse by bargaining collectively. The Agricultural Fair Practices Act explicitly protects the right of individual farmers to join cooperative organizations to preserve their marketing and bargaining position, stating that ''[i]nterference with this right is contrary to the public interest and adversely affects the free and orderly flow of goods'' (7 U.S.C. 2301).

Non-cooperative associations and organizations are also core activities under the Act deserving of protection

[137] *See e.g.,* ''Farmers should be able to participate in producer organizations and associations. Farmers have expressed concern that associations, organizations and the farmers who join them have repeatedly been targets of retaliatory behavior by meat companies. When farmers participate in these organizations it helps fill in the information gap for their business and keeps our economic markets competitive.

Farmers and Ranchers should be able safely participate as witnesses in any proceeding relating to violations of the Packers and Stockyards Act. Unfortunately, there are recent examples of cattle rancher witnesses who were threatened and intimidated so much that they decided not to testify before Congress at a hearing about cattle markets. The ability to testify without fear of retaliation is essential to promoting fair and competitive markets in the livestock and poultry industries.'', available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0299; see also,* ''The ability to express an opinion and testify without fear of retaliation is essential to promoting healthy, fair and competitive markets in the livestock and poultry industries, as it is in all aspects of a free and fair democracy.'', available at *https://www.regulations.gov/comment/AMS-FTPP-21-0045-0297*.

[138] *See e.g.,* 61 Cong. Rec. H1860 (1921).

[139] 7 U.S.C. 291.

against regulated entity coercion because they afford covered producers the opportunity to combine their resources to potentially counteract market imbalances and capture opportunities at scale. For example, they provide a means for covered producers to share information regarding the production of poultry and livestock (within permissible scope of the Federal antitrust laws) even when a cooperative is not feasible. They also enable producers to potentially uncover and address problematic practices in the industry, including through working together to reduce the risk of seeking redress of grievances, among other benefits. Some producer associations also provide means for producers to obtain lower cost inputs, such as gasoline. AMS believes that retaliating against producers for engaging in these activities hinders the free flow of information and hampers producers' ability to fairly compete in the market and realize full value of their livestock and poultry. An assertion of rights in both these contexts may involve expressing interest or intent to engage in these activities or engaging in these activities.

Paragraph (b)(2)(iii) also protects a covered producer's right to refuse to join a producer or grower association or organization. AMS added protection for refusing to form or join a producer or grower association or organization in response to public comment on the proposed rule, as commenters noted that producers have experienced pressures from regulated entities to join certain organizations that may express views or interests in the livestock or poultry industry that are contrary or not fully reflective of the producer's views regarding their own interests.

Paragraph (b)(2)(iv) protects a covered producer's ability to communicate or cooperate with a person for the purposes of improving production or marketing of livestock or poultry. ''A person'' is intended to be broad, and includes USDA's Extension and other academic experts, businesses and associations, advisors and associates of the covered producer, other covered producers, including someone under contract with the same regulated entity. This regulation protects a covered producer's ability to communicate or cooperate with other persons, including efforts to obtain higher or otherwise more appropriate compensation from regulated entities, to the extent permissible under Federal antitrust laws and cooperative laws. Protecting such communications enables the producer to obtain help to enhance their ability to compete in the market. Such communication may include, for example, communication with extension programs or with independent veterinarians and animal health experts. It would also include communications with persons—including other producers—relating to potential illegal market abuses, anticompetitive conduct, or otherwise illegal conduct by regulated entities, as that conduct would obstruct the covered producer's ability to secure the full value of their livestock or poultry product or services. AMS notes that communications on these matters when with the government would be protected by paragraph (b)(2)(i), and would include but not be limited to communications with: USDA; the U.S. Department of Justice; the Federal Trade Commission; a State or Tribal attorney general or agriculture department; or a Federal, State, or Tribal legislative office or committee or judicial tribunal.

Paragraph (b)(2)(v) protects a covered producer's ability to communicate, negotiate, or contract with a regulated entity, another covered producer, a commercial entity, or a consultant for the purpose of exploring or entering into a business relationship. The purpose of the provision is to preserve and promote the competitive position of the covered producer and ensure that a regulated entity's retaliation does not discourage a covered producer from seeking competitive alternatives. It affords producers the opportunity to realize the full market potential of their products and services and participate in the market fully, including through price discovery and competition between multiple regulated entities. For example, a covered producer may want to seek information from a regulated entity with which they do not currently have a business relationship regarding the possibility of a future business relationship, such as entering into a contract. Or, a covered producer may enter into a contract to sell livestock in the market or through an auction or exchange. Protecting these activities allows covered producers to freely compare potential business relationships and choose between several regulated entities, encouraging competition. As also discussed in Section V—Changes from the Proposed Rule, communications of this type can improve production efficiency and price discovery mechanisms. Restricting participation in these activities forecloses full market participation by producers.

Paragraph (b)(2)(vi) protects a covered producer's ability to support or participate as a witness in any proceeding under the Act or any proceeding that relates to an alleged violation of any law by a regulated entity. Because of the close-knit and concentrated markets in which covered producers operate, AMS believes that protecting some covered producers as witnesses may enable other covered producers to effectuate their rights under the Act and related laws, which would improve market integrity in the markets governed by the Act. Without such protections, enforcement of the Act may be frustrated overall.

Finally, paragraph (b)(2)(vii) protects a covered producer's ability to assert any of the rights granted under the Act or the regulations in 9 CFR 201, or to assert rights afforded by their contract. These rights include, for example, producers' rights to view the weighing of flocks, which is legally protected but which producers have complained is not practically enforceable. In the 2010 USDA–DOJ public workshop on the poultry market, a grower said he was retaliated against for asserting his right to view his flock being weighed; the integrator ''cut me off from growing business and cost me hundreds of thousands of dollars.'' [140] Although these rights are ostensibly protected by laws, regulations, or legal contracts, they lose their efficacy if covered producers suffer repercussions for asserting them.

Section 201.304(b)(3) enumerates the actions that are retaliation or an otherwise adverse action under paragraph (b)(1) of this section. The final rule intends to capture the widest range of conduct harmful to producers, where such harms are based upon activities protected by the rule. The focus in any inquiry under this final rule is whether the regulated entity has engaged in harmful conduct in whole or material part because a covered producer engaged in any protected activity. To provide examples of what activities are materially harmful to a reasonable covered producer, paragraph (b)(3) sets out that regulated entities are prohibited from (i) terminating or not renewing a contract with a covered producer; (ii) performing under or enforcing a contract differently than with similarly situated covered producers; (iii) requiring a contract modification or a renewal on terms less favorable than those for similarly situated covered producers; (iv) refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers; (v) interfering in farm real estate transactions or contracts with third

[140] Accessed at *https://www.justice.gov/media/1244676/* on 10/03/2023.

parties; (vi) taking any other action that a reasonable covered producer would find materially adverse.

Paragraph (b)(3)(i) prohibits terminating or not renewing a contract with a covered producer because the covered producer has engaged in protected activities. This practice can have devastating consequences for producers that have invested substantial sums in infrastructure that only meets the requirements of a particular regulated entity. Furthermore, in concentrated markets, losing a contract may put a producer out of business as the producer has few, if any, other livestock or poultry buyers to whom they can sell livestock or poultry.

Paragraph (b)(3)(ii) prohibits performance under or enforcement of a contract differently as compared to performance under or enforcement of contracts for similarly situated covered producers as retaliation for engaging in protected activity. Depending on the facts and circumstances of the case, the ''similarly situated producer'' could be the covered producer's own status quo prior to engaging in the protected activity. A violation of this regulation would occur when a regulated entity, in response to a producer engaging in protected activities, inconsistently enforces its contracts compared with contract enforcement for similarly situated producers. For instance, the Agency has received complaints over the years with respect to differential performance under poultry growing arrangements, such as the delivery to affected growers of flocks that are sick or otherwise known to be likely to perform poorly owing to the age of the hens, differential delivery of feed, or other differential treatment such as early or delayed harvest of birds. Those actions are likely to result in lower performance for the grower in a poultry grower ranking system, which results in lower pay for the grower. While that may occur from time to time per natural cycles, a repeated or intentional delivery of underperforming flocks has been commonly reported as a principal means of adversely affecting grower earnings. Accordingly, AMS has incorporated differential contract performance to capture those contractual performance-based means that a regulated entity may use to retaliate against producers for engaging in protected activities.

Paragraph (b)(3)(iii) prohibits requiring a contract modification or a renewal on terms less favorable than those for similarly situated covered producers as retaliation for engaging in protected activity. Depending on the facts and circumstances of the case, the similarly situated producer could be the covered producer's own status quo prior to engaging in the protected activity. In this final rule AMS seeks to clarify that unfavorable contract modification or renewal by a regulated entity, if it's the result of a producer engaging in a protected activity, is retaliatory conduct and amounts to a violation under the Act. This behavior is a common way for regulated entities to retaliate against producers by, for example, reducing the number of flocks or their density, changing types of birds raised, or otherwise changing contract terms that result in lower incomes for growers. As another example, if a regulated entity requires a capital investment from a covered producer as part of a contract modification or contract renewal that the regulated entity is not requiring of similarly situated producers, this requirement would be a violation of paragraph (b)(3)(iii) if the regulated entity is requiring the capital investment in retaliation for the covered producer's participation in a protected activity.

Paragraph (b)(3)(iv) prohibits refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers. A violation of this regulation could occur if a regulated entity makes no reasonable effort to bid or negotiate or fails to reasonably attempt to contract in good faith with a covered producer, due in whole or material part to a producer's prior, or current, participation in protected activities. In this context, the regulated entity's refusal to deal is not connected with the service or quality of the product offered, but rather is material in part due to the producer exercising his or her rights to engage in protected activities. A similarly situated producer may, depending on the facts and circumstances, be the producer's own prior status quo with the regulated entity before the producer engaged in a protected activity. This provision includes scenarios in which cattle producers operate in the cash market for livestock. While some cattle producers may only be in the cash market a few times a year, others may be in the cash market weekly. In the latter case, this provision would cover certain types of retaliation. If a producer sells cattle to a particular packer every week, and then one week the packer refuses to buy the producer's cattle or offers significantly less favorable terms after the producer engaged in a protected activity, this would constitute retaliation under this rule absent evidence of changed business conditions necessitating the packer's refusal to deal. AMS believes that retaliating against a producer in this way is conduct the Act seeks to remedy because it raises a barrier to competitive entry to the market by decreasing the number of parties a producer can do business with, which in effect is a market failure.

Paragraph (b)(3)(v)'s prohibition on interfering with a covered producer's farm real estate transactions or with their contracts with third parties is a prohibition against conduct that a regulated entity may engage in due to the unequal power dynamic that exists between producers and the few firms available for them to contract with. This conduct may take several forms but has been observed most commonly to occur when a producer attempts to sell its farm to a third party and in doing so must terminate or fail to renew their existing contract with a regulated entity. In these situations, the regulated entity may choose not to guarantee a similar contract, or any contract at all, to the prospective buyer. Without this guarantee, banks and prospective buyers are unlikely to enter the farm real estate transaction because the land is of little use to them without a contract to grow livestock or poultry. This is often seen in the poultry sector, where it is alleged that regulated entities use the potential transfer of farm real estate as an opportunity to require growers to make capital improvements in exchange for their guarantee to contract with the new grower. This becomes retaliatory because the unreasonable refusal to guarantee a future contract with a prospective landowner or operator dramatically lowers the value of the farm operation, to the point of obstructing the transfer of the real property by the landowner, and yet the debt burden on the farm is commonly incurred in response to the regulated entity's requests for additional capital investments. The seller of farm real estate faces an unjust extraction, or else they are unable to sell land, as the cost of capital improvements required by the regulated entity in exchange for a guarantee to contract with a new owner or operator is not a freely-determined agreement. Farm sales transactions are not, however, the only circumstance where a regulated entity can retaliate against a covered producer through contracts with third parties. For example, covered producers have sought to develop new marketing opportunities for their livestock and poultry through collectively processing their product. If the regulated entity sought to obstruct the sale of the meat or poultry products through distribution or retail chains as retaliation against a

covered producer with a material interest in the meat or poultry sales organization, that interference would be covered by this rule.

Paragraph (b)(3)(vi) prohibits any other action that a reasonable covered producer would find materially adverse. This regulation is designed to account for a broader scope of actions that are considered retaliatory. Under this provision any conduct would be considered prohibited retaliation if such conduct caused material harm to the covered producer relative to the covered producer's situation prior to the allegedly retaliatory conduct, or relative to conduct toward similarly situated producers. This provision provides a broad and flexible approach to these prohibitions and allows for ''material'' to be determined by the facts and circumstances of each case. As discussed under Section V—Changes from the Proposed Rule, some retaliatory activities may occur outside the confines of contractual relationship, for example, a regulated entity's interference in a covered producers' water rights. The provision also covers the act of making a threat to engage in an action where the threat can reasonably be foreseen to change the producer's conduct or where the threat delivers a reasonable possibility of material harm.

When regulated entities punish covered producers or deny them opportunities afforded to other covered producers for engaging in certain activities, it is an unjustly discriminatory practice. Not only do retaliatory practices harm individual covered producers; recurrent instances and patterns of retaliation erode market integrity and discourage fairness and competition in the livestock and poultry markets. Under § 201.304(b), AMS is providing greater clarity, specificity, and certainty as to how the Act applies with respect to retaliatory behavior. This will facilitate higher levels of compliance by regulated entities, enable AMS to better enforce the Act, and position producers to better assert their rights under the Act.

D. Recordkeeping (§ 201.304(c))

Paragraph (c)(1) of § 201.304 requires that a regulated entity retain all records relevant to its compliance with the prohibitions on discriminatory behavior contained in paragraphs (a) and (b) of this section. Records must be retained for no less than five years from the date of record creation. Paragraph (c)(2) states that relevant records may include policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, board of directors' oversight materials, and the number and nature of complaints received relevant to this section.

Recordkeeping is a commonly used regulatory compliance and monitoring mechanism among market regulators.[141] The recordkeeping requirement in this rule is not new. AMS currently has the authority to require regulated entities to create, maintain, release to AMS, and dispose of records through the Act and its regulations, including sec. 401 of the Act and 9 CFR 201.94, 201.95, and 203.4. Section 401 of the Act requires regulated entities to keep ''such accounts, records, and memoranda as fully and correctly disclose all transactions involved in his business . . .'' (7 U.S.C. 221). Such records may include details of a single transaction, such as the name of the owner of the livestock or poultry, date, weight of livestock or poultry, number of head of livestock, and unit price; all elements necessary to recreate the total sum paid to the producer or grower by the regulated entity. Existing regulations under 9 CFR 201 require regulated entities to give the Secretary ''any information concerning the business . . .'' (§ 201.94) and provide authorized representatives of the Secretary access to their place of business to examine records pertaining to the business (§ 201.95). Section 203.4 is another relevant existing regulation with respect to the types of records to be kept by regulated entities and the timelines for disposal of these records by the regulated entities.

Existing gaps in both generally applicable agricultural and PSD-specific data collection make addressing widespread reports of discriminatory behavior difficult. Access to the types of records required by § 201.304(c) will assist AMS in assessing the effectiveness of a regulated entity's compliance with § 201.304(a) and (b). Therefore, this recordkeeping requirement is critical for AMS to fulfill its duties to prevent, and if necessary secure enforcement against, undue and unreasonable prejudice and unjust discrimination.

AMS believes that this recordkeeping approach—at both the regulated entity policy and procedural level, as well as at the transactional level—will enable the Agency to monitor and facilitate a regulated entity's approach to compliance. Recordkeeping will encourage regulated entities to adopt more robust compliance practices to stamp out conduct prohibited by the Act in its incipiency. It will also enable AMS to uncover conduct that violates the rule in any investigation—a deterrent which will also strengthen compliance. AMS underscores that the tone and compliance practices set by senior executives play a vital role in establishing a corporate culture of compliance, which is a critical first step toward more inclusive market practices. Thus, relevant records may include those at the highest levels, such as relevant accountability practices of the board of directors. In addition to the importance of policies and procedures in developing a corporate culture of compliance, this rule maintains that transactional records, where decision-making occurs, are also important records to keep and to help AMS understand why an adverse action was taken against a producer or grower by a regulated entity. These records may include the number and nature of complaints received relevant to this section; in addition to records already required to be retained under § 203.4, such as buyers' estimates; buying or selling pricing instructions and price lists; correspondence; telegrams; or teletype communications and memoranda relating to matters other than contracts, agreements, purchase or sales invoices, or claims or credit memoranda.[142]

AMS is requiring that records be retained for five years from their creation date to provide a broader ability to monitor the evolution of compliance practices over time in this area, and to ensure that records are available for what may be complex evidentiary cases. While providing the authority for regulated entities to keep certain records, sec. 401 of the Act does not provide guidance on when records can be disposed. Existing regulation at 9 CFR 203.4 provides for a disposal date of two years, with an exception for certain records that may be disposed of after one year. This rule extends the disposal date of most records from two years to five years to promote efficient USDA monitoring efforts. For some records, the current disposal date is one year, which could be extended to five years under this rule if they are deemed relevant to showing compliance with this rule. Most records, such as specified in sec. 401, ''such accounts, records, and memoranda as fully and

[141] *See, e.g.,* generally, Board of Governors of the Federal Reserve System, ''Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices,'' *Consumer Compliance Handbook,* available at *https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf* (last accessed June 2022).

[142] eCFR: 9 CFR part 203—Statements of General Policy Under the Packers and Stockyards Act.

correctly disclose all transactions involved in his business . . .'' are currently kept for two years and will be extended to five years. Other particular records that, if kept, will be required to be kept five years instead of the current one year, including, for example, buyers' estimates; buying or selling pricing instructions and price lists; correspondence; telegrams; or teletype communications and memoranda relating to matters other than contracts, agreements, purchase or sales invoices, or claims or credit memoranda.

E. Deceptive Practices (§ 201.306)

Section 201.306 is designed to broadly address deceptive practices in the marketplace by establishing four categories where deceptive practices commonly occur: contract formation, contract performance, contract termination, and contract refusal. Overall, the final rule addresses areas of concern regarding deception in contracting but does not exhaustively identify all deceptive practices that violate sec. 202(a) of the Act. Through this rule AMS aims to promote a marketplace that is free from the type of injury the Act was designed to prevent. False or misleading statements, or omissions of material information, during the contracting process or operation or termination of that contract, are prohibited deceptive practices because they prevent or mislead sellers or buyers from making informed decisions concerning their livestock or poultry operations. Deception puts honest businesses at a competitive disadvantage; and may even cause them to adopt deceptive practices.[143] To capture a range of longstanding approaches to deception that USDA has taken under the Act, AMS is prohibiting the use of false or misleading statements, or omission of material information during contract formation, performance (including enforcement or not enforcement of the contract), and termination. This rule also prohibits regulated entities from providing false or misleading information to a covered producer or a producer association concerning a refusal to contract. During this rulemaking process, AMS also considered the FTC's interpretation of sec. 5 of the FTC Act regarding deceptive acts or practices, ''FTC Policy Statement on Deception.''[144] Like sec. 202(a) of the Act, sec. 5 of the Federal Trade Commission (FTC) Act also prohibits deceptive practices. In 1983, the FTC adopted the aforementioned policy statement summarizing its longstanding approach to deception cases.[145] In this final rule, AMS references that policy statement because it offers useful guidance owing to the similarity of the statutory provision and case law history. In addition, AMS recognizes the benefits to the practical application of this final rule by grounding it on the well-understood principles of deception identified in the FTC policy statement.[146]

More than 100 years of history illustrate the types of conduct prohibited as deceptive by the Act, which provides a foundation for some of the specific deceptions that this rulemaking addresses. The regulations implemented by this rulemaking are not the first to prohibit deception. Current regulations under the Act require honesty in weighing (9 CFR 201.49 and 201.71), price reporting (§ 201.53), fees (§ 201.98), and business relationships (§ 201.67). Even when considering whether termination of a contract violated the Act, AMS currently considers the quality of the communication, and therefore considers its honesty (see § 201.217). Past cases indicate that USDA's approach, generally, is to view representations, omissions, and practices from the perspective of a reasonable party receiving them and determine if those deceptions affect the conduct or decision of the recipient. As the court explained in *Gerace* v. *Utica Veal Co.,*[147] a regulated entity is liable to anyone for the damages its deceptive practices cause, even if the entity is not a direct party to the transaction.

AMS aims to have regulated entities be truthful and straightforward—that is, not misleading—in their dealings with producers. With § 201.306, AMS seeks to uncover the true motive for a regulated entity's treatment of a producer with whom they are forming or have a contractual relationship. Whether contract language was clear and written in a language the producer understands will be part of any evaluation to determine whether a statement (including any omission) was false or misleading; that determination will be dependent on the particular facts and circumstances of the contract. Violations of the Act that would constitute deceptive practices include false statements or omissions that are material in that they prevent sellers or buyers from making an informed business decision.[148] Thus, obvious falsehoods, such as false weighing and false accounting, have always been considered deceptive practices under sec. 202(a) of the Act. Another obvious falsehood—delivering checks drawn on accounts with insufficient funds, whether for livestock or meat—is also deceptive. Moreover, the Act requires honest dealing, so misleading omissions of material information necessary to make a statement not false or misleading are also prohibited. Prohibited omissions include failure to tell a business partner that the regulated entity was receiving a commission from a competitor,[149] sales records that omit relevant information,[150] or failure to have the required bond.[151] And finally, where regulated entities have close business relationships, kickbacks and bribes undermine the ability of producers and consumers to rely on an honest market and are therefore deceptive.[152]

Producers should not be misled with respect to their business decision-making with regulated entities. Deception can prevent producers from obtaining the full value of their products and services. In markets pervaded by deception, formerly honest businesses may be compelled to adopt deceptive practices if they are to remain competitive.[153] Moreover, in a concentrated market, if producers are misled regarding why regulated entities take certain actions, in particular refusing to deal with them, they cannot

[143] *FTC* v. *Winsted Hosiery Co.,* 258 U.S. 483 (1922) See also, ''Businesses that accurately represent the total amount consumers will pay up front are at a competitive disadvantage to those that do not,'' from FTC–2022–0069–6095 (describing harm to competition and honest businesses through price obfuscation). p. 77432, *https://www.federalregister.gov/documents/2023/11/09/2023-24234/trade-regulation-rule-on-unfair-or-deceptive-fees.*

[144] FTC Policy Statement on Deception, 1983. Available at *https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.*

[145] Ibid.

[146] Kades, Michael. ''Protecting Livestock Producers and Chicken Growers,'' Washington Center for Equitable Growth, May 2022, *https://equitablegrowth.org/research-paper/protecting-livestock-producers-and-chicken-growers/.*

[147] 580 F. Supp. 1465, 1469 (N.D.N.Y. 1984).

[148] FTC Policy Statement on Deception, 1983. Available at *https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.* (''Third, the representation, omission, or practice must be a ''material'' one. The basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service.'').

[149] 9 CFR 201.61.

[150] 9 CFR 201.43; 9 CFR 201.99.

[151] 9 CFR 201.29.

[152] 9 CFR 201.56; 9 CFR 201.67; 9 CFR 201.71.

[153] Michael Kades, ''Protecting livestock producers and chicken growers,'' *Washington Center for Equitable Growth* (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf* (''Subversion of normal market forces by fraud, deception, unfair conduct, or market manipulation undermines the integrity of the market and deprives producers of the true value of their livestock,'' p. 55.)

plan or mitigate the risks they may face. For these reasons, this final rule establishes a robust regulatory framework prohibiting deceptive practices in a range of contracting circumstances. Such a framework should provide a broad, although non-exhaustive, set of prohibitions to provide greater certainty for producers and regulated entities alike in the integrity of business dealings in the livestock and poultry markets.

Paragraph (a) of this section sets forth the scope of the prohibition on deceptive practices by establishing that the prohibitions contained in paragraphs (b) through (e) of § 201.306 apply to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. This phrasing, which has been used in previous rules under the Act, points to the broadest possible interpretation of the Act's jurisdiction over regulated entities' conduct.

Section 201.306(b) prohibits a regulated entity from making or modifying a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading. Preventing false or misleading representations, express or implied, or failing to provide the necessary information necessary to make a representation not misleading during the contracting process, are some of the most basic protections of the integrity of the marketplace. ''By employing'' captures the materiality of the false or misleading representation in that the representation formed a material part of the action under making or modifying the contract. Case law applying the Act illustrates some of the forms of deception that regulated entities may take during the offering or formation of a contract with producers. While some consumer-focused cases under the Act have addressed false advertising—specifically bait-and-switch advertising that occurs through advertising on price when, in fact, the customer has to pay a higher price at the point of sale,[154] a regulated entity's failure to disclose information to a covered producer has also been held to be deceptive under certain circumstances. The Act's purposes include protecting farmers and ranchers from receiving less than fair market value for their livestock and protecting consumers from unfair practices. Among the means employed to accomplish this purpose is the use of surety bonds. Sellers of livestock are entitled to the protection of a packer, dealer, or market agency's surety bond securing its obligations. Failure to maintain an adequate bond is therefore a deceptive practice.[155] When a packer fails to maintain a bond, the seller does not know that the sale is unsecured, and therefore the seller is at greater risk of nonpayment.

Deception in contract formation is not limited to false statements and omissions with respect to regulatory requirements. The Act includes affirmative duties to be truthful. For instance, in *Schumacher* v. *Tyson Fresh Meats, Inc.,* the court recognized that the Act prohibits a regulated entity from negotiating by using published prices it knows are inaccurate because using incorrect prices deceives the livestock seller. In *Schumacher,* the packer failed to disclose to sellers inaccurately reported boxed beef prices when it negotiated the purchase of cattle based on those prices. The court found that those deceptive practices violate the Act.[156] Likewise, *Bruhn's Freezer Meats of Chicago, Inc.* v. *U.S. Dept. of Agriculture,* affirmed that a variety of deceptive practices violate the Act, including short weighing, misrepresenting grades and cuts of meat, and false advertising in the selling of meat to customers.[157] The Agency's regulation with respect to deceptive practices in contract formation prohibits all these types of deception.

Section 201.306(c) prohibits a regulated entity from performing under or enforcing a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading. It is fundamental to the integrity of the marketplace and critical during the performance or enforcement of contracts that regulated entities are prohibited from making false or misleading representations—express or implied—and that they are prohibited from failing to provide the necessary fact or information necessary to make a representation not misleading. ''By employing'' captures the materiality of the false or misleading representation in that the representation formed a material part of the action under performing or enforcing the contract.

Deceptive practices take many forms throughout the operation of a contract. USDA and the courts have recognized these forms in a variety of administrative and Federal enforcement actions, including false weighing, false or deceptive grading (including failure to disclose the formulas for determining payment), failure to pay for purchases, and pretextual refusals to deal.

False or inaccurate weighing has long been recognized as deceptive under secs. 202(a) and 312 of the Act.[158] False weighing can occur in various ways. In some cases, the regulated entity records inaccurate weights using an improperly calibrated scale. In other cases, a regulated entity uses the scale improperly. In all these cases, false weighing is a plain and straightforward instance of a false statement that is material to the reasonable producer. Even if a regulated entity does not intentionally set out to deceive with respect to the weight of livestock, the Act does not require proof of a particularized intent.[159] Short weighing alone is enough to be an unfair and deceptive practice under the Act, without regard to the competitive injury the short weighing causes.[160]

False or inaccurate grading has the same effect as false weighing because deceptive grading prevents the seller from receiving the full value of their livestock or poultry. A USDA Judicial Officer found a deceptive practice when a packer failed to inform hog producers of a change in the formula it used to estimate lean percent in hogs. Lean percent was one factor used in determining price when the packer purchased hogs on a carcass merit basis. USDA determined that nearly twenty thousand lots of hogs were purchased under the changed formula without notice to producers, resulting in payment of $1.8 million less than they would have received under the previous formula.[161] This type of deceptive practice harms honest competitors because ''[h]ad hog producers been alerted to the change, they could have shopped their hogs to other packers.'' [162]

Payment violations can also be deceptive, especially issuance of

[154] *In re: Larry W. Peterman, d/b/a Meat Masters,* 42 Agric. Dec. 1848 (1983), *aff'd Peterman* v. *United States Dep't of Agric,* 770 F.2d 888 (10th Cir. 1985).

[155] *United States* v. *Hulings,* 484 F. Supp. 562, 567 (D. Kan. 1980). *See also In Re: Mid-W. Veal Distributors,* 43 Agric. Dec. 1124, 1139–40 (1984), *citing In re: Norwich Veal and Beef, Inc.,* 38 Agric. Dec. 214 (1979), *In Re: Raskin Packing Co.,* 37 Agric. Dec. 1890, 1894–6 (1978).

[156] *Schumacher* v. *Tyson Fresh Meats, Inc.,* 434 F.Supp.2d 748 (Dist. S.D. 2006).

[157] *Bruhn's Freezer Meats,* 438 F.3d 1337 (8th Cir. 1971).

[158] See *Bruhn's Freezer Meats,* 438 F.3d 1337 (8th Cir. 1971); *Solomon Valley Feedlot,* 557 F.2d at 717; *Gerace* v. *Utica Veal Co.,* 580 F. Supp. 1465, 1470 (N.D.N.Y. 1984).

[159] *Parchman* v. *U.S. Dep't of Agric.,* 852 F.2d 858, 864 (6th Cir. 1988) (interpreting sec. 312 of the Act).

[160] *Garace,* 580 F. Supp. At 1470.

[161] *In re: Excel Corporation,* 63 Agric. Dec. 317 (2004), aff'd *Excel Corp.* v. *United States Dep't of Agric.,* 397 F.3d 1285, 1293 (10th Cir. 2005).

[162] 397 F.3d at 1291.

insufficient funds checks. For example, regulated entities may withhold payment to prevent producers from commencing legal action or reporting otherwise unrelated violations to authorities.[163] Failing to pay for meat has also been found to be deceptive in numerous instances.[164] Under the similar language of secs. 312 of the Act, the Eighth Circuit explained that lack of timely payment was unfair and deceptive even prior to the enactment of sec. 409 of the Act: ''Timely payment in a livestock purchase prevents the seller from being forced, in effect, to finance the transaction.'' [165]

Section 201.306(d) prohibits a regulated entity from terminating a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading. Employing false or misleading representations, express or implied, or failing to provide the necessary fact or information necessary to make a representation not misleading—critical protections during the performance or enforcement of contracts—are similarly fundamental to the integrity of the marketplace. ''By employing'' captures the materiality of the false or misleading representation in that the representation formed a material part of the action under performing or enforcing the contract. AMS draws on its experience in establishing the need for this prohibition. AMS notes, for example, that poultry growers complain of companies terminating their broiler production contracts based on pretext or for a deceptive reason. Contract termination puts the grower at severe risk of significant economic loss. The potential loss includes not only the loss of production income but also a grower's farm or family home, since a production broiler house construction is often financed with mortgages on those assets. Pretextual cancellation, in the form of false or misleading representations or material omissions, may also make even the sale or transfer of the broiler production house impossible because purchasers may be unable to determine if the broiler houses have value.

AMS included the prohibition against false or misleading information or material omissions in paragraphs (b) through (d) to protect producers from conduct that employs deceit to disguise a regulated entity's genuine motive. A poultry producer stated in a public workshop that he relied upon cash flow statements provided by the integrator to secure a loan for his operation only to find out later ''that the document wasn't accurate from the first flock that I placed and set. The capital investment of these facilities, while they may be greatly benefiting the integrator, are not returning any value to us whatsoever.'' [166] In another public comment, a poultry producer asserted that he is ''not given a clear picture of the integrator's operating procedures until after a contract has been signed. The contracts are very biased and one-sided, giving the bulk of control and authority to the initiator of the contract and then, only after you have committed to playing their game you are then given the rule book.'' [167] The producer further stated that, ''the practices of the integrators are very calculated to ensure the integrators are protected legally while entrapping the farmer into modern day indentured servitude.'' [168]

Section 201.306(e) prohibits a regulated entity from providing false information to a covered producer or association of covered producers concerning a refusal to contract. Deception related to refusal to contract is an unlawful practice designed to exclude producers from livestock and poultry markets. For example, if a producer association is asking on behalf of its members why a regulated entity is not executing any deals in the cash market and the entity lies about why it is avoiding the cash market, this could impede market entry for the association's members. Owing to the risk of retaliation, even with this final rule in place, a covered producer may depend upon a producer association to obtain the necessary understanding why the regulated entity is engaging in certain practices in the market, such as refusing to contract with covered producers.

A regulated entity that refuses to contract on unlawful grounds may well choose to hide their motives with misleading or deceptive statements. This regulation recognizes false and misleading statements made as justification of a refusal to enter into a contract as ''deceptive'' within the meaning of the Act. However, when refusing to enter into a contract, a regulated entity is not required to explain its reasoning so long as it does not offer a false or misleading statement to a covered producer.

Producers and consumers cannot make rational decisions in a dishonest market, and honest competitors cannot compete when regulated entities deceive. With this rulemaking, AMS is adding § 201.306 to its existing deception regulations under the Act to provide a broad array of coverage regarding the general circumstances that encourage the provision of false or misleading information in contracting. This regulation does not provide an exhaustive list of instances of deceptive practices; rather, it establishes four categories where deceptive practices commonly occur. The intent is to provide guidance to covered producers on how to effectuate their rights under section 202(a) of the Act and to promote a marketplace that is free from the type of injury section 202(a) was designed to prevent. AMS will investigate any alleged violations of this regulation and its determination will depend on the facts and circumstances of each case.

F. Severability (§ 201.390)

AMS is adding § 201.390, ''Severability,'' to new subpart O to confirm that if any provision of subpart O, or any component of any provision, is declared invalid or if the applicability thereof to any person or circumstances is held invalid, it is AMS's intention that the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby with the remaining provision, or component of any provision, to continue in effect. Such a provision is typical in AMS regulations that cover several different topics and is included here as a matter of housekeeping.

This rule aims to address concerns around unduly prejudicial, unjustly discriminatory, retaliatory, and deceptive conduct in the livestock and

[163] *See, e.g., In Re: Mid-W. Veal Distributors, d/b/a Nagle Packing Co., & Milton Nagle,* 43 Agric. Dec. 1124, 1140 (1984).

[164] *See, e.g. Milton Abeles, Inc.* v. *Creekstone Farms Premium Beef, LLC,* No. 06–CV–3893(JFB)(AKT), 2009 WL 875553, at *19 (E.D.N.Y. Mar. 30, 2009) (*citing Liberty Mutual Ins. Co.* v. *Bankers Trust Co.,* 758 F.Supp. 890, 896 n. 7 (S.D.N.Y.1991); *In re FLA Packing & Provision, Inc., and C. Elliot Kane,* P & S Docket No. D–95–0062, 1997 WL 809036, at *6 n. 1 (1997); *In re: Central Packing Co., Inc. d/b/a Plat–Central Food Services Co., Inc., a/k/a Plat–Central Food Service Supply Co., and Albert Brust, an individual,* 48 Agric. Dec. 290, 297–99 (1989)); *see also In Re: Ampex Meats Corp. & Laurence B. Greenburg.,* 47 Agric. Dec. 1123, 1125 (1988) (*citing In Re: Rotches Pork Packers, Inc. & David A. Rotches.,* 46 Agric. Dec. 573, 579–80 (U.S.D.A. Apr. 13, 1987) *In Re: George Ash,* 22 Agric. Dec. 889 (1963); *In re Goldring Packing Co.,* 21 Agric. Dec. 26 (1962); *In Re: Eastern Meats, Inc.,* 21 Agric. Dec. 580 134 (1962)).

[165] *Van Wyk* v. *Bergland,* 570 F.2d 701, 704 (8th Cir. 1978).

[166] United States Department of Justice, United States Department of Agriculture. May 2010. Public Workshops Exploring Competition in Agriculture, Poultry. Accessed at *https://www.justice.gov/media/1244676/dl?inline* on 10/03/2023. p. 366.

[167] Rural Advancement Foundation International (RAFI), ''Comment on AMS–FTPP–21–0045: Inclusive Competition and Market Integrity Under the Packers and Stockyards Act,'' available at *Regulations.gov*.

[168] *Ibid.*

poultry industry to the broadest jurisdiction of the Act. This new subpart has two sections that prohibit unduly prejudicial, unjustly discriminatory, and deceptive practices. This regulation is intended to take a series of regulatory actions, within this rulemaking, to address several different harms on the same or similar subjects but not prohibit identical conduct. The wrongful conduct addressed in the undue prejudice and discrimination, retaliation, and deception provisions are each different—the first focusing on adverse action on the basis of a personal characteristics or status of the producer, the second on certain protected actions by the covered producer, and the third focused on deception in contracting. AMS included these provisions based on the likelihood that conduct falling within one or more of these sections will stifle honest competition or exclude independent livestock producers, poultry growers, and swine contractors from the marketplace. Each provision could, however, have been implemented on a stand-alone basis without the others. Conduct that violates one provision is not dependent on protections put in place in other sections. For example, if a regulated entity discriminates against a producer on the basis of a protected class in an unduly prejudicial manner, AMS may enforce the regulation without alleging violations of retaliation or deception. These new provisions are written so that they are not mutually exclusive. Furthermore, the benefits of each provision of this rule are not diminished by the absence of a different provision. For example, the benefits of protecting producers against retaliation are not lost if the rule is held to fail to protect against deception or discrimination.

AMS intends that the severability provision operate to the fullest extent possible. AMS recognizes that—to a limited extent—not all the language of the rule is severable. For example, to find undue prejudicial discrimination under ''race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, or marital status, or age of the covered producer,'' the prejudicial conduct must be ''on the basis of'' one of the specified protected bases. AMS recognizes that this causation requirement is not severable as it is integral to that specific provision of the rule.

However, AMS intends that all other portions and components of the rule may be severable without affecting the remaining portions of the rule, and that the rule remains workable and continues to serve the interests of the agency's policy goals. For instance, AMS intends that the invalidity or unenforceability of one of the rule's prohibited bases does not render the others invalid or unenforceable. The protected bases have different reasons for their appearance in the rule. For example, if the protected base of religion were found invalid or unenforceable, this does not negate the benefits of including protections for another protected base, like sex. Also, to further follow this example, the language in § 201.304(a)(1)(i) is severable from those included in the retaliation (§ 201.304(b)) and deception (§ 201.306) sections. Therefore, one or more provisions might be unenforceable as to an individual or a specific case, but AMS intends that the remaining provisions would still be enforced. Finally, if determining the necessity of an individual provision to the enforceability of its entire section, and the benefits of that section are still intact without an unenforceable provision, AMS would intend to retain the enforceable provisions.

VII. Comment Analysis

AMS received 446 public submissions in response to the proposed rule. Numerous comments to the proposed rule expressed concerns that concentrated, vertically integrated markets expose producers to exclusion from the market on bases unrelated to the quality of their products or services and that the markets in which the commenters operate lack sufficient honesty, integrity, and fair dealing. In addition, numerous comments stated that, except for very narrow justified circumstances, there are no competitive benefits to these practices when operating within a market where producers are less able to compare, negotiate, or change business relationships.

Other commenters were critical of the proposed rule. Some commenters expressed disagreement with the need for the proposed rule, arguing that it is duplicative of the Act and existing regulations, while other commenters stated that the proposed rule's vagueness would make compliance a challenge. Other commenters argued that the proposed rule would result in costly litigation and recordkeeping burdens and exceeded AMS's authority under the Act.

The public comments are summarized by topic below and include AMS's responses.

A. Definitions (§ 201.302)

AMS proposed to add definitions in § 201.302 for *covered producer, livestock producer, market vulnerable individual, and regulated entity.* AMS received comments about the proposed definitions of *livestock producer* and *market vulnerable individual.* Comments about the latter are addressed below in Section VII.C.i—Market vulnerable individual approach.

In § 201.302, AMS proposed to define *livestock producer* as any person engaged in the raising and caring for livestock by the producer or another person, whether the livestock is owned by the producer or by another person, but not an employee of the owner of the livestock. AMS proposed to add a new definition of *covered producer* to encompass livestock producers as defined in this section, along with swine production contract growers and poultry growers as defined in sec. 2(a) of the Act.

Comment: Several commenters noted the proposed definition of *livestock producer* could include individuals only tangentially related to livestock production, such as accountants working for feed yards, truck drivers hauling livestock owned by others, veterinarians, nutritionists, or consultants. The commenters contended the proposal opens the definition of *livestock producer* to an unlimited number of litigants beyond the scope of the Act.

Similarly, a meat industry trade association said AMS should withdraw or amend the definition of *livestock producer* because its vagueness potentially adds so many individuals to the covered producer umbrella as to be unworkable. Another association noted its confusion when reading the definition, given that the definition's wording explicitly excludes employees of the owner of livestock, but includes anyone who is not an employee of the owner of livestock that is engaged in raising or caring for livestock.

AMS Response: AMS is revising the definition of *livestock producer.* AMS intended that the term livestock producer be defined in a manner similar to other terms in the Act, so that the protections of the rule would fit violations that are described in this rulemaking. Under the final rule, *livestock producer* is defined as any person—except an employee of the livestock owner—engaged in the raising of and caring for livestock. As commenters noted, the proposed definition was vague and potentially confusing. The revised definition provides clarity by removing unnecessary and potentially confusing phrasing. In response to commenters' concerns that the term encompasses individuals only tangentially related to livestock production, AMS has revised

the proposed definition to focus this final rule on the Agency's traditional role in protecting the producer to the fullest extent possible under the Act—including but not limited to production and marketing. To the extent that the producer is harmed through acts that the regulated entity takes against an employee acting as agent for the producer or another entity that the covered producer utilizes or relies on for production or marketing, the producer could still fully benefit from the protections of this final rule. Whether the non-producer parties could benefit from the protections of the Act may depend upon particular facts and circumstances.

B. Applicability

AMS proposed in §§ 201.304 and 201.306 to apply its prohibitions on undue prejudice, retaliation, and deceptive practices to swine contractors and live poultry dealers as defined in sec. 2(a) of the Act and to packers as defined in sec. 201 of the Act. Proposed § 201.304(a)(1) would prohibit prejudice, disadvantage, or the denial or reduction of market access by regulated entities against covered producers based on their status as ''market vulnerable'' producers. AMS requested comment on whether the prejudicial discrimination and retaliation provisions should be extended to all persons buying or selling meat and meat food products, including poultry, in markets subject to the Act.

Comment: An agricultural advocacy organization expressed support for AMS's proposal to extend protections to all covered producers who experience retaliation by regulated entities.

An agricultural advocacy organization said that if AMS adds aspects of regional concentration and aspects of contract growing arrangements, such as high debt load, to the definition of a market vulnerable individual, then the proposal to provide protection based on market vulnerable individual status is appropriate. This commenter noted that AMS's question regarding extension of the prejudicial discrimination and retaliation provisions highlights the need for a separate rule addressing enforcement of the Act's prohibition on undue preferences. According to this commenter, if AMS makes it clear that it intends to enforce the Act to stop companies from giving undue preferences to some sellers, everyone participating in these markets will have adequate protection.

AMS Response: AMS appreciates the comments regarding a broader definition of MVI to include all those impacted by the abusive conditions aggravated by market concentration. AMS recognizes that producers face challenges because of consolidated market power, including from types of conduct this rule aims to address. One of the purposes of this rule is to address adverse impacts of concentrated markets by ensuring inclusive competition free of unjust discrimination on the basis of race, color, religion, national origin, sex, disability, or marital status, or age or because of the covered producer's status as a cooperative, as well as to protect against retaliation and deception.

AMS underscores that the protections for cooperatives are intended, in part, to help producers gain market leverage in the face of concentrated markets. In 1922 Congress passed the Capper-Volstead Act providing legal protections for producers to collectively process, prepare for market, handle and market their products. Cooperatives enable smaller, disparate producers to band together, coordinate in ways that otherwise may not be permissible under the antitrust laws outside of a single company, and otherwise work together to obtain a better bargain from market counterparties with larger economic footprints. AMS will continue to work toward addressing problems associated with concentration through subsequent rulemaking. USDA is also utilizing other tools to address undesirable business practices born from market concentration that adversely impacts producers. USDA is investing $1 billion to support greater choice for producers through expanded local and regional processing capacity in meat and poultry. USDA has also announced enhancements to its antitrust enforcement partnerships, including investing in partnerships with DOJ through farmerfairness.gov and with more than 32 State attorneys general, updates to its meat and poultry labels that will better guard against misbranding that damages the signals that flow from consumers to producers, as well as other agency actions intended to address unfavorable behavior by regulated entities facilitated by concentration in the livestock industry.

However, addressing unjust discrimination solely on the basis of the size or indebtedness of the producer is outside the scope of this rule, and because of the complex economic implications of volume preferences and efficiencies, would be more appropriately considered in the context of a future update to undue preferences rules. In contrast, undue and unreasonable prejudice or disadvantage on the basis of the prohibited bases and protected activities adversely affects allocative efficiency and offers no competitive benefits. That is true irrespective of whether the unlawful conduct occurs in a concentrated market or not.

AMS has shifted away from its market vulnerable approach and has adopted a well-established standard in line with existing economic, civil rights, and other regulatory regimes that rely on protected bases for discrimination. Producers with high debt loads are not included in those well-established protections; therefore, AMS will not include them in its final rule.

C. Undue Prejudices and Unjust Discrimination (§ 201.304(a))

AMS proposed new provisions in § 201.304(a) that would prohibit regulated entities from prejudicing, disadvantaging, or inhibiting market access, or otherwise taking adverse action against a livestock producer, swine production contract grower, or poultry grower based on the producer's status as a ''market vulnerable individual'' or as a cooperative.

i. Market Vulnerable Individual Approach

AMS proposed to prohibit prejudicing, disadvantaging, inhibiting market access, or otherwise taking adverse action against covered producers based on their status as a *market vulnerable individual (MVI).* It proposed to define that term as a person who is a member, or who a regulated entity perceives to be a member, of a group whose members have been subjected to, or are at heightened risk of, adverse treatment because of their identity as a member or perceived member of the group without regard to their individual qualities. A market vulnerable individual would include a company or organization where one or more of the principal owners, executives, or members would otherwise be a market vulnerable individual. When defining *market vulnerable individual* in its proposal, AMS listed a non-exhaustive list of protected classes that would be considered market vulnerable such as race, ethnicity, or sex or gender prejudices (including discrimination against an individual for being lesbian, gay, transgender, or queer), religion, disability, or age.

AMS requested comment on whether the regulatory protections provided by the prohibition on undue prejudices for market vulnerable individuals and cooperatives would assist those producers in overcoming barriers to reasonable treatment, or otherwise address prejudices or threats of prejudice in the marketplace. It further requested comment on whether specific

groups should be named as market vulnerable individuals, whether AMS should identify defined protected classes, or whether AMS should use a ''market vulnerable producer'' approach, which extends broad antidiscrimination protections to any producer belonging to a group subjected to or at heightened risk of adverse treatment. In addition, it requested comment on whether it should delineate specific examples of groups that are market vulnerable, as well as supportive evidence regarding historical adverse treatment of such groups. Finally, it requested comment on whether the undue prejudices provision of the proposed rule provides sufficient protection regardless of the covered producer's type of business organization.

Comment: Several commenters indicated proposed § 201.304(a) would provide necessary protections, consistent with the Act, against packers and processors who leverage their market power to injure marginalized farmers. Farm bureaus and other agricultural advocacy organizations also indicated the rule would protect producers from certain prejudices, unjust discrimination, retaliation, and deceptive practices.

Several commenters stated they preferred the market vulnerable producer approach to fighting discrimination over the traditional protected classes approach because it would allow for flexibility to address different markets and different forms of prejudice and discrimination that may develop. An agricultural and environmental organization stated the market vulnerable producer approach not only covers instances of discrimination based on protected characteristics such as race, national origin, sex, religion, gender identity, and disability, but can also apply to other forms of discrimination unique to livestock and poultry markets. This commenter said this approach is consistent with the Act, which prohibits ''any'' unjust discrimination, and ''any'' undue prejudice or disadvantage ''in any respect whatsoever.'' Several State attorneys general suggested that the proposed definition was preferable as proposed, without specifying traditional protected classes, because it would allow for flexibility among different markets and forms of prejudice or discrimination that may develop over time.

Several agricultural advocacy organizations said poultry and cattle producers operating in regions with monopsony or oligopsony conditions should qualify as market-vulnerable individuals. Similarly, an academic or research institution sought to add producers operating in monopsony conditions to the definition. A commenter suggested AMS use the regional Herfindahl-Hirschman index to indicate the market vulnerable status of producers in a region. Some commenters cited heightened risk of adverse treatment as a rationale for considering these groups to be market vulnerable or noted that monopsony power has been legally relevant in cases under the Act and there is judicial precedent for acknowledging monopsonist power as a factor in adverse impacts to competition, while others said these groups meet the criteria laid out by AMS in the preamble to the proposed rule explaining why historically marginalized groups are likely to be vulnerable to market abuses.[169] The latter commenter provided detailed evidence that these groups met each of the criteria AMS identified: their relative ''size, sales, and incomes;'' their ''exposure to concentrated market forces;'' their having ''fewer economic resources'' to ''counteract'' adverse market structures; and their ''isolation'' from economic networks such as sources of supply, other producers, and distribution.

Several commenters seeking protections for producers that are at increased risk of being disadvantaged due to highly concentrated regional markets cited Colorado cattle producers as an example, given the USDA has not publicly reported the State's fed cattle prices for several years because there are too few packers purchasing fed cattle in Colorado to overcome USDA confidentiality guidelines. Commenters noted, with few packers in the region, sellers in the region are vulnerable to unfair practices.

An agricultural advocacy association recommended that AMS expand the MVI definition to include covered producers whose geographic locations restrict their ability or willingness to sell and transport their livestock to two or fewer regulated entities. This commenter also said that it would be helpful for AMS to expand on and provide more ''definite form'' to the four socioeconomic factors presented in the rulemaking notice. The association reasoned that if producers can proactively demonstrate their status as market vulnerable, it would avoid the need for ad hoc microeconomic analyses or expert witnesses to make assessments on individual bases.

Several State attorneys general suggested AMS specifically address the vulnerability that small, rural farmers encounter due to their location or production size. The commenters stated small, rural farmers do not have enough local processors, and those processors give preference to packer-owned and contract livestock for the limited packing plant capacity available. An agricultural advocacy organization also said small, independent cattle producers meet many of the criteria for being considered market vulnerable, arguing for example that they are exposed to concentrated market forces because they do not receive forward contracting arrangements from packers; they are denied favorable bonus, financing, and risk sharing terms common with other arrangements; and they are required to sell their cattle to packers on at-will cash markets for lower aggregate compensation. Agricultural advocacy organizations also said independent cattle producers operating in cash-negotiated spot markets should be considered vulnerable because of their independent status. Other commenters recommended AMS expand market vulnerable individual status to include non-English speakers, people with limited education, producers in markets with limited buyers, and immigrant farmers.

Agricultural advocacy organizations recommended the definition of market vulnerable individual explicitly include, but not be limited to, race, color, national origin, religion, sex, sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or gender identity. Commenters asserted individuals in each of these groups should not have to continually prove discrimination and prejudice against them based on the characteristic that makes them vulnerable in the market.

Agricultural advocacy organizations expressed support for including cooperatives in the prohibited bases under proposed § 201.304. These commenters recommended that AMS explain in the preamble to the final rule the relationship between the producer association protections under the Agricultural Fair Practices Act and the proposed new protections under the Act, noting regulated entities have unjustly discriminated against covered producers based on their membership in these cooperatives due to the increased market leverage these cooperatives or other producer associations provide.

An individual commenter urged AMS to explicitly prohibit discrimination based on sexual orientation and gender identity for those who voluntarily disclose such status. The commenter

[169] 87 FR 60020–21, October 3, 2022.

stressed AMS should not require LGBTQ producers to disclose their sexual orientation or gender identity in conducting business, citing privacy, and security concerns. Other commenters noted sexual orientation is different from gender identity, so both should be listed individually in the rule.

Some agricultural and environmental advocacy organizations expressed support for AMS's flexible ''market vulnerable individual'' approach, but also expressed concern that the proposed rule would impose a difficult burden of proof on covered producers, requiring, for example, a producer alleging discrimination based on their status as a member of a historically marginalized group (*e.g.,* a racial minority) to also demonstrate their status as a market vulnerable individual ''in relevant markets.'' Commenters indicated producers should not have to continually prove they are being discriminated against if they are members of a protected class or qualify as a market vulnerable individual. These commenters urged AMS to clarify the Act directly prohibits discrimination based on protected class status and to provide producers with guidance on how to demonstrate their market vulnerable status. Commenters recommended that AMS include in § 201.304 a non-exhaustive list of factors covered producers can rely on to demonstrate their market vulnerable status.

Similarly, agricultural advocacy groups recommended that AMS clearly identify the types of individuals the agency would consider to be market vulnerable, and the methodology AMS will use to make this determination. A commenter specified producers who derive a substantial percentage of their income from their livestock or poultry operation are more vulnerable to unjust practices than those who derive a small percentage of their income from those operations. A commenter suggested that AMS develop a method to assess regional concentration levels using information regarding market share, Herfindahl-Hirschman index, and price reporting systems to allow producers to show they operate in a region that qualifies them as market vulnerable individuals.

An organization urged AMS to revise proposed § 201.304(a)(1) to clarify that the rule bans discriminatory conduct based on disparate treatment or disparate impact, not just discriminatory intent. According to the commenter, while secs. 202(a) and (b) of the Act clearly establish that the determinative factor for whether conduct constitutes a violation is its purpose or effects, the proposed language in § 201.304(a)(1) potentially requires a covered producer to prove discriminatory intent. The commenter said that, by describing prohibited conduct using the verb forms of ''prejudice,'' ''disadvantage,'' ''inhibit market access,'' and ''take adverse action,'' this language suggests the proposed rule would only prohibit actions motivated by a prohibited basis. Therefore, the commenter recommended that AMS revise this section to use language that parallels the text of sects. 202(a) and (b) in clearly distinguishing the actions of regulated entities from their discriminatory nature or effects.

Some commenters who supported AMS's market vulnerable producer approach expressed concern that the proposed rule could place a heavy burden on producers to establish an intentional discrimination claim based on market vulnerable status, citing the DOJ, among others, in noting that successfully showing discriminatory intent can be extremely difficult.[170] According to the commenters, producers would have evidence of differential treatment, but they would not likely have evidence to show they were subject to adverse treatment because of their status as market vulnerable individuals. Therefore, these commenters urged AMS to require regulated entities to rebut a presumption of discriminatory intent once a producer demonstrates differential treatment. Specifically, the commenters recommended the final rule include provisions clarifying that, to prove an unlawful violation of § 201.304(a), producers must demonstrate that they meet the definition of a ''market vulnerable individual'' or are a member of a protected class, and that they were personally subject to disparate and adverse treatment. One commenter also said producers' burden here should include showing circumstantial facts plausibly suggesting a causal connection between their group identity and the treatment they received. The burden would then shift to the regulated entity to show that the producer's market-vulnerable status was not a motivating factor for its presumptively discriminatory conduct, and the same decision would have been made regardless of the producer's market vulnerable status. The commenters cited case law in asserting this burden-shifting approach is consistent with other antitrust and civil rights evidentiary frameworks developed by the courts to reduce the burden of proving discriminatory intent.[171]

A commenter also asked AMS to establish a separate liability standard and burden-shifting framework for discriminatory-effects claims. The commenter said AMS should introduce a framework analogous to the Department of Housing and Urban Development's (HUD) Discriminatory Effects Standard,[172] under which a covered producer would have the initial burden of demonstrating that a regulated entity's policy or practice causes or predictably will cause a discriminatory effect. The commenter said the burden should then shift to the regulated entity to show that the challenged practice is necessary to achieve a substantial, legitimate, and nondiscriminatory interest which could not be served by another practice with a less discriminatory effect. The commenter also provided further details about what would constitute a discriminatory effect or a legitimate interest under this standard.

A plant worker offered three factors to consider when determining market-vulnerable groups. These factors included being a member of any ''socially disadvantaged group'' as defined by the USDA Farm Bill,[173] working for a small producer (no formal definition of ''small producers'' was offered), or being in geographic areas with an ''ultra-high'' concentration of buyers that leads to increased buyer market power and reduced prices paid to producers.[174]

Some commenters expressed opposition to the proposed definition of market vulnerable individual on the basis that it was too vague. An association asserted the definition is ''so vague that neither party may be able to figure out whether the contract grower is indeed a 'market vulnerable individual.' '' Commenters said the proposed definition implicates the Due Process Clause, with commenters saying the definition as drafted is so open-

[170] U.S. Department of Justice, Civil Rights Division, *Title VI Legal Manual,* 5. *See also Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 271 (1989) (''[D]irect evidence of intentional discrimination is hard to come by.'').

[171] *See Impax Labs., Inc.* v. *Fed. Trade Comm'n,* 994 F.3d 484, 497–500 (5th Cir. 2021); *McDonnell Douglas Corp.* v. *Green,* 411 U.S. 792 (1973).

[172] Reinstatement of HUD's Discriminatory Effects Standard, 86 FR 33590, June 25, 2021 (to be codified at 24 CFR part 100).

[173] According to the commenter: ''A group whose members have been subjected to racial or ethnic prejudice because of their identity as members of a group without regard to their individual qualities.''

[174] Matthew C. Weinberg *et al.,* ''Buyer Power in the Beef Industry,'' *https://equitablegrowth.org/grants/buyer-power-in-the-beef-industry.*

ended that it could potentially include any producer, thus giving processors inadequate notice of when they might be in danger of violating the proposed rule. Commenters suggested AMS intends for courts to flesh out the specifics on who the rule covers, noting this approach would lead to more uncertainty and confusion. Commenters also said the definition is vague because it incorporates inherently subjective concepts, such as whether a producer is a member of a group ''whose members are at heightened risk of adverse treatment.'' Commenters questioned what amount of risk constitutes ''heightened risk.''

Two cattle industry trade associations and a live poultry dealer contended that the ambiguity of the definition would create uncertainty for regulated entities when making market vulnerable-status determinations on a case-by-case basis, which could disincentivize bringing on new producers in the future. They argued that AMS could avoid this uncertainty if it introduced codified standards based on consistent immutable traits, such as protected classes.

Some commenters were opposed to explicitly including protected classes in the definition. A meat industry trade association noted that it can be difficult or impossible for regulated entities to ascertain all the demographic information for every producer they do business with to determine whether the producer they are contracting with is in a protected class and thus a market vulnerable individual. An agricultural association noted that regulated entities soliciting such demographic information could in and of itself give the appearance of discriminatory behavior.

Lastly, some commenters opposed the *market vulnerable individual* definition because they thought it would be too limiting. Two farm bureaus argued that it would create uncertainty for producers who do not meet the definition, and that protections should be available for anyone participating in the marketing of livestock. Other farm bureaus also suggested that *market vulnerable individual* be defined solely by economic factors, rather than social factors, to be consistent with the objectives of the Act.

AMS Response: AMS, in response to these comments, has decided not to use *market vulnerable individual* as the basis for the rule's prohibition on discrimination or undue or unreasonable prejudicial or disadvantageous action. AMS agrees that the term MVI may be too vague, ambiguous, and overly broad to serve as the prohibited basis for undue or unreasonable prejudice. Instead, this rule uses protected classes largely as defined by ECOA, plus disability and status as a cooperative, as the bases against which unjust discrimination or undue prejudice is prohibited because, as explained above in Section VI—Provisions of the Final Rule, this regulation incorporates the ECOA terms with respect to discrimination in the extension of credit because those terms reflect USDA policy against discrimination in conducted programs.[175] Protections against discrimination on these protected bases extend to all producers. AMS, incorporating feedback from producers and other stakeholders, decided to create its protected bases on the well-established ECOA standards, with some additions. Regarding the commenter's concern that regulated entities may not be aware of the demographic information of producers with whom they conduct business, in such cases AMS would not be able to prove discriminatory conduct because any adverse action taken against that producer could not have been on the basis of their status as a protected class.

AMS adopted several suggestions by commenters regarding the specific bases for protection against unjust discrimination. Principally, AMS's authority to clarify the protected bases stems from sec. 407 of the Act, which authorizes the Secretary to ''make such rules, regulations and prescribed orders as may be necessary to carry out the provisions of this Act.'' [176] The Act has incorporated provisions of other law (such as the FTC Act and the Clayton Act). The Act is a remedial statute that prohibits unlawful discrimination. To inform the scope and bases of unlawful discrimination and prejudice under the Act in this rulemaking, AMS has looked to other civil rights laws, which aid in determining the scope of discrimination and prejudice that is unjust and undue. AMS concludes here that discrimination and prejudice on the bases set forth under this final rule inhibit the ability of all to participate in the market, and that the clarifications set forth in this final rule are necessary to protect all market participants from unjust discrimination and undue prejudice. Furthermore, AMS has considered available relevant references to support the determination. These include USDA's Statement on Conducted Programs [177] and evidence of a general congressional policy found in ECOA that prohibits discrimination on the bases of race, color, religion, national origin, sex (including sexual orientation and gender identity), marital status, age, or disability. Additionally, AMS is including status of a covered producer as a cooperative as a prohibited basis of discrimination because Congress, through passage of the Capper-Volstead Act, has provided clear statutory support for cooperatives as an organizational form that allows farmers to achieve scale through coordination and thereby more effectively compete in agricultural markets and engage with other market participants. AMS is adopting the aforementioned specific bases, as opposed to MVI, because the specific prohibited bases offer clearer, more workable standards that will facilitate compliance by regulated entities and better enable producers to exercise their rights under the Act.

The use of those terms comes with well-established jurisprudence in other contexts, such as ECOA, which incorporates the Act's enforcement provisions, appropriately applied in the context of livestock and poultry markets. Additionally, the status of covered producer as a cooperative was added to the list of protected classes against which discrimination is prohibited. The prohibition on discrimination covers cooperatives consistent with and in furtherance of the Agricultural Fair Practices Act. Cooperatives enable smaller producers' ability to balance concentrated economic power through their ability to coordinate and negotiate.

AMS will not include degrees of market concentration within particular geographic locations in its list of protected bases. Doing so would give rise to difficult questions around whether the government should restrict the ability of regulated entities to seek efficiency based on production volume, which is outside of the scope of this rule.

Additionally, AMS will not include in its list of protected bases a size component for the same reasons that it is not incorporating market concentration or geographic location. Nor is AMS including a prohibition against discrimination in markets with limited buyers. In both cases, such a prohibition would likely result in an all-encompassing rule that would swallow this rule's intent to protect specific well-established classes and activities which are widely utilized across multiple

[175] 15 U.S.C. 1691c(a)(5).

[176] Packers and Stockyards. Act, 1921. Packers and Stockyards. Act, 1921 (Aug. 15, 1921, ch. 64, title I, § 1, 42 Stat. 159.) Section 407.

[177] USDA's Statement on Conducted Programs, accessed 1/30/2024.

economic and civil rights regulatory regimes to stop market exclusion and enable producers to realize the full value of their animals. AMS underscores that the agency is aware of and sensitive to the concerns that smaller producers face greater challenges in the face of concentrated markets, where, as commenters suggested, small rural farms are at a disadvantage when competing with larger operations in their sale of livestock to a limited number of packers.

In this rule, AMS does not address questions of discrimination based on the type of contract a producer has with a regulated entity for the sale of their livestock. Considerations raised in that type of discrimination, revolving around how livestock is marketed, are different from the considerations undertaken in this rule around whether the producer's personal characteristics are a prohibited basis of unjust discrimination. Nonetheless, AMS is aware that some producers may be under pressure to enter forward contacts or AMAs and that this may limit their access to markets. AMS is considering other rules that may be more appropriate for addressing those concerns.

Additionally, AMS intends for non-English-speaking producers and immigrant producers to be covered under the prohibition on discrimination on the basis of national origin or, in some cases, race if they are facing discrimination on those bases. Therefore, AMS need not expressly include non-English speaking producers in this rule. However, people with limited education are not included as protected bases because enforcement of such discrimination offers certain practical challenges and is not well defined in other areas of law.

In this final rule, AMS has expressly prohibited discrimination based on sexual orientation by adding that term as well as gender identity to the prohibited basis of sex. The Supreme Court in *Bostock* v. *Clayton County* recognized that to discriminate against a person based on sexual orientation or transgender status is to discriminate against that individual based on sex.[178] AMS has included the term sex as part of its prohibition on discrimination. By expressly adding ''including sexual orientation and gender identity'' to the rule text, AMS confirms that sex includes those forms of discrimination. Therefore, sexual orientation and transgender status are covered.

[178] *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020).

Nor is disclosure a requirement for discrimination based on sex. If a regulated entity takes adverse action that amounts to undue prejudice against a person on the basis of sex, it is immaterial whether the decision is based on an accurate or inaccurate assessment of the actual gender or sexual orientation of the covered producer. In either instance, this prejudice is undue under the regulation.

In terms of concerns raised by commenters about the burden to establish a claim, producers will not have to prove their status as a market vulnerable individual as originally proposed as the bases of discrimination are now based on discrete types of protected classes. Therefore, as suggested by commenters responding to the proposed rule, AMS does not need to provide a non-exhaustive list of factors for covered producers to demonstrate their market vulnerable status.

Furthermore, because market vulnerability is no longer a consideration when assessing violative conduct, AMS is not using market vulnerability as a basis for assessing whether unjust discrimination has occurred in violation of the Act. As noted above, this final rule will not address discrimination on the basis of geographical location, regional concentration, or size of a producer's operation because this rule is focused on prohibiting adverse actions on bases for which there are no pro-competitive benefits. Differences in treatment based on geographic location, regional concentration, or size of the producer's operation all raise more challenging tradeoffs with respect to competitive benefits. To the extent that a covered producer suffers discrimination on those bases, AMS encourages the covered producer to report the concern to PSD, including through the tips and complaints portal *farmerfairness.gov,* for consideration on a case-by-case basis under the Act.

AMS is not establishing a formal burden-shifting framework in this rule, nor one specifically focused on discriminatory effects such as an analysis of disparate impact. Rather, AMS will leave the development of evidentiary proof to the facts and circumstances of specific cases and to the tribunals' processes and burdens for producing evidence. AMS has investigatory and enforcement capabilities to determine whether violative conduct has occurred under the Act. AMS's investigative powers are extensive and include the ability to examine regulated entities' records and compel testimony. AMS may investigate to determine whether a regulated entity's disparate treatment of a producer was on the basis of a protected class as specified in this regulation.

Moreover, as described in Section V—Changes from the Proposed Rule, subsection D—Retaliation Provisions, AMS changed ''because of'' to ''based upon.'' Paragraph (b)(1)'s prohibition as ''based upon'' is intended to be broader than ''but for'' causation and so capture when the protected characteristics or status are a material, or non-trivial, element of the decision to take an adverse action against a covered producer. AMS expects that fact-finding tribunals will establish the necessary processes for proving these elements, with an eye toward the protections for covered producers and for open, inclusive markets that this rule is designed to provide. AMS underscores that discriminatory intent is not an element of this final rule and need not be shown to establish a violation, for example, where the regulated entity cannot proffer a non-discriminatory business reason that fully justifies the adverse action, or where the producer can show that such reason offered was pretextual, a sham, or otherwise does not negate the presence of the prohibited bases as a material element of the action.

Comment: An academic institution expressed support for AMS's efforts to protect historically disadvantaged groups within the stockyard and packing industries but suggested it may be more effective to address the barriers to entry these groups face related to the specialized education and training required by these industries. The commenter recommended that AMS make agricultural and industry-specific training and education more accessible to minority populations.

AMS Response: This rule is designed to strengthen the regulatory protections afforded to producers by the Act. AMS intends to conduct education and outreach to producers to help them understand their rights under these acts. Additionally, greater access to specialized training and education could be helpful to stopping market exclusion of underserved producers. AMS and other USDA agencies conduct a range of programs to support producer education, with the goal of remedying market exclusion of underserved producers. However, providing specialized training oriented toward enabling members of historically disadvantaged groups to become more effective livestock producers is outside the scope of this rulemaking.

ii. Proposed Rule Is Unnecessary

Comment: Several industry associations contended the proposed rule is duplicative and therefore not necessary. According to these commenters, the conduct addressed in the proposed rule is already prohibited under the Act and existing regulations, citing the ''Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyard Act'' final rule (the 2020 Rule).[179] The commenters explained the 2020 Rule identifies factors for determining whether disparate treatment of similarly situated producers is justified. If the disparate treatment is not justified, it is likely to be deemed an undue or unreasonable preference. Commenters noted the proposed rule would prohibit several forms of disparate treatment of covered individuals, indicating proposed § 201.304(a)(2) would make it a violation for a regulated entity, in dealings with covered producers, to prejudice, disadvantage, inhibit market access, or otherwise take adverse action. Examples of prejudice or disadvantage specified in the proposed rule include offering less favorable contract terms than are customarily offered; refusing to deal; differential contract performance or enforcement; or termination or non-renewal of a contract. According to the commenters, these actions are already prohibited under § 201.211 because they are not justified based on cost savings, based on meeting a competitor's terms, or as a business decision.

An industry association asserted establishing antidiscrimination law under the proposed rule is unnecessary because civil rights laws already are well-established. The commenter also contended the proposed rule would not address the market inequities faced by producers not included in the protected classes, and the vague proposed definition of market vulnerable individual would likely result in litigation creating additional hardship for the individuals the rule seeks to protect.

An individual indicated the proposed rule would not be effective in addressing prejudices or threats of prejudice in the marketplace and instead recommended AMS take action to create more packers, which would facilitate greater market access.

AMS Response: AMS agrees with the commenters that the conduct at issue is prohibited under the Act and, in some circumstances, could be enforceable under existing rules and regulations. However, AMS disagrees with commenters who said this rule is duplicative of the 2020 Rule. In response to the proposed rulemaking that preceded the 2020 Rule,[180] AMS received numerous comments raising concerns regarding discriminatory and retaliatory practices; however, AMS stated that the 2020 Rule was published for the narrow purpose of establishing criteria to consider when assessing whether a violation of sec. 202(b)'s prohibition against undue preferences or unreasonable advantages occurred.

The 2020 Rule established four criteria the Secretary will consider when determining whether conduct by packers, swine contractors or live poultry dealers represents an undue or unreasonable preference or advantage. Those criteria include whether the preference or advantage cannot be justified on the basis of a cost savings related to dealing with different producers, sellers, or growers; cannot be justified on the basis of meeting a competitor's prices; cannot be justified on the basis of meeting other terms offered by a competitor; and cannot be justified as a reasonable business decision. However, as set forth in the rule itself, the criteria are not exhaustive and not determinative. The rule offers limited guidance regarding how it is to be applied.

The 2020 Rule did not include the prohibited bases of discrimination set forth in this rule because it asserted that they were undue prejudices, rather than undue preferences, which are distinct prohibitions in the statutory text.[181] Specifically, the 2020 Rule's preamble noted that discrimination on the basis of race, gender, and other such protected bases was unlawful and would be addressed under the Act's prohibition against undue prejudices.[182] In August 2021, AMS reiterated this policy in a series of Frequently Asked Questions (FAQs).[183] This final rule affirms that approach, in that the 2020 Rule clarifies undue preference while this rule clarifies undue prejudice. Moreover, this rule provides clarity, specificity, and certainty in the application of the Act, which will facilitate compliance and enforcement by regulated entities and better inform covered producers of their protections under the Act.

AMS is not aware of a separate Federal law or rule that would cover the circumstances outlined in this final rule. This rule sets forth how certain adverse actions by regulated entities give rise to unjust discrimination and prejudice that, on their face, are unjust and undue and undermine a competitive market. This rule addresses the unique and often difficult-to-prove discriminatory conduct that has long existed in the agricultural sector by prohibiting specific bases of prejudicial action. In doing so, AMS is clarifying the application of the Act, better empowering producers to protect themselves, and encouraging companies to adopt more robust compliance practices to snuff out prohibited conduct prohibited by the Act in its incipiency, before, in the aggregate, it can distort markets. In particular, this rule addresses the longstanding and often difficult-to-counter forms of exclusion that have plagued the agricultural sector for decades. AMS intends for this rule to support positive trends toward inclusivity in the marketplace. As noted above, all commenters, including industry commenters, affirmed that prejudices on the basis of race, color, religion, national origin, sex, age, disability, and similar bases have no place in today's modern agricultural markets.

Demographic information is seldom recorded in agricultural transactions; therefore, it is difficult to quantify discrimination, unlike in other sectors such as housing and banking. Furthermore, in highly concentrated agricultural markets with few minority participants, further defining the Act to include a list of prohibited bases of unjust discrimination helps ensure fair competition for all farmers. This rule will help all producers better understand their rights under the law and come forward when they recognize instances of unjust discrimination. This rule will help USDA to better enforce the Act. In addition, as AMS has determined not to use the market vulnerable individual approach in the final rule, commenter concerns that the definition for market vulnerable individual will lead to litigation are moot.

AMS acknowledges one commenter's recommendation that AMS take action to reduce concentration in the meatpacking industry and create more packers, with the goal of facilitating greater market access for livestock and poultry operations. This recommendation was made out of skepticism that the rule would change

[179] 85 FR 79779, December 11, 2020.

[180] 85 FR 1771.

[181] *Montclair* v. *Ramsdell,* 107 U.S. 147, 152 (1883) (Courts should ''give effect, if possible, to every clause and word of a statute, avoiding, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language it employed'').

[182] 85 FR 79787.

[183] USDA, Agricultural Marketing Service, ''Frequently Asked Questions on the Enforcement of Undue and Unreasonable Preferences under the Packers and Stockyards Act,'' August 2021, *https://www.ams.usda.gov/rules-regulations/packers-and-stockyards-act/faq.*

conduct by regulated entities and substantially enhance market access for covered producers. While not directly addressing this specific recommendation, AMS is including a recordkeeping requirement to support evaluation of regulated entity compliance and thus facilitate effective enforcement of the statute. The USDA has also taken a number of steps to support small meat processors, including through hundreds of millions of dollars invested to support competition in the processing market.

iii. Specific Challenges or Burdens Regulated Entities May Face in Complying With Proposed Undue Prejudices Provisions

AMS asked about specific challenges or burdens regulated entities may face in complying with the undue prejudice provisions of the proposed rule. It also requested comment on how the undue prejudices provisions differ from existing policies, procedures, and practices of regulated entities.

Comment: Industry commenters said the vague terms in the proposed rule present an additional challenge for compliance. Commenters cited unclearly defined terms such as ''inhibit market access'' and ''adverse action,'' saying they make it impossible for regulated entities to determine what constitutes a violation and how to comply with the proposed regulations. Similarly, commenters noted it is not clear how the regulated entity would determine whether contract terms are ''less favorable,'' or how contracts executed at different times, in different regions, or in different economic conditions would be compared.

AMS Response: ''Inhibit market access'' means excluding producers from livestock and poultry markets outright or erecting barriers to market access that prevent producers from earning the full value of their animals. AMS rejects the need to define ''adverse action'' because this would too greatly constrain the application of the regulation. Based on its regulatory experience, AMS believes regulated entities are fully aware of when their economic interactions with covered producers, including contracting, the operation of contracts, termination of contracts, or refusing to deal, result in adverse economic outcomes for producers. However, to provide greater clarity, the final rule provides greater specificity with respect to prohibited actions as set forth in § 201.304(a)(2), as described earlier.

The scope of prohibited conduct regarding adverse actions is clarified by the shift from market vulnerable individual to membership in a protected class as the prohibited bases of unjust discrimination; the focus of the inquiry should be on those bases. If a regulated entity offers a covered producer less favorable contract terms principally or substantially because the covered producer belonged to one of the protected classes, it violates the law and this rule.

iv. Sufficient Addressing of Concerns Regarding Tribal Members, Tribes, and Tribal Government Entities That Sponsor or Manage Regulated Entities

AMS requested comment on whether the provisions on undue prejudice adequately address concerns regarding inequitable market access for Tribal members and Tribes. It also requested comment on how it should handle Tribal government entities that sponsor or manage regulated entities. AMS asked whether it should permit compliance with proposed § 201.304(a) to be substituted for compliance with Tribal government rules, policies, or guidance governing equitable market access.

Comment: Commenters urged AMS to consult with Tribal organizations engaged in agricultural policy and livestock production projects, such as the Intertribal Agricultural Council and the Native Farm Bill Coalition.

AMS Response: AMS engaged in an extensive Tribal Consultation pursuant to USDA and Federal treaties governing U.S. relations with Indian Tribes. AMS's principal conclusion was that Tribal governments have important duties to serve their members that may require them to treat non-Tribal members less favorably. Accordingly, AMS has established a legitimate business justification as an exception to the prohibition of unjust discrimination against covered producers on the bases of protected classes (race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, age of the covered producer or the covered producer's status as a cooperative) when the regulated entity is a Federally-recognized Tribe, including its wholly or majority-owned entities, corporations, or Tribal organizations, that is performing Tribal governmental functions. The agency describes its rationale for creating this exception in greater detail above, as well as below under the Tribal Consultation section.

v. Treatment of Private Industry Programs Aimed at Establishing Preferences Intended To Address Systemic Inequality

AMS requested comment related to private industry programs aimed at establishing preferences intended to address systemic inequality by partnering with Black producers or similar programs designed to address socially inclusive supply chains. It asked whether, if such programs were present in livestock and poultry markets, it should evaluate them and determine them to be undue preferences pursuant to the criteria in 9 CFR 201.211. It also requested suggestions on ways to address relevant concerns.

Comment: Agricultural advocacy organizations indicated this question relates to what is considered an ''undue'' preference. The commenters noted a program, practice, or policy that provides opportunities to producers who have been vulnerable to unfair market practices in the past may be a justified form of preference rather than an undue preference.

AMS Response: AMS takes note of the commenters' belief that a justified preference would likely apply in those circumstances and that this rule governs undue or unreasonable prejudices or disadvantages. As discussed above, the 2020 Rule establishes criteria for the Secretary to consider when assessing whether a preference is undue. To the extent that there may be situations where the 2020 Rule and this final rule would arguably both apply, AMS would take a facts-and-circumstances approach to decide which rule applies. Accordingly, AMS makes no change.

vi. Appropriateness of Proposed Rule's Protection for Cooperatives

AMS requested comment on whether the proposed regulation would provide appropriate protection for cooperatives, particularly with respect to the fact that their structure and organization varies across livestock and poultry markets.

Comment: A group of State attorneys general and an academic institution expressed support for the proposed protection for cooperatives, noting these protections will ensure small farmers can continue to compete in the market. Agricultural advocacy organizations recommended AMS revise the reference to ''cooperative'' in proposed § 201.304(a)(1) to refer to ''cooperatives or other association of producers'' because many producer associations designed to give covered producers more leverage in the market are not structured as cooperatives, noting this recommended change is consistent with

the producer association definitions related to the protections provided in the Agricultural Fair Practices Act.[184]

AMS Response: AMS has included cooperatives as a class protected against prejudice or unjust discrimination because cooperatives are an important tool for smaller producers to countervail the market power of regulated entities, whether due to market concentration or the inherent power imbalance that exists in livestock supply chains between a small number of processors and a much larger number of producers. This inclusion of cooperatives as a protected class reaffirms the strong statutory authority Congress has provided cooperatives in agricultural markets, as manifested by its passage in of the Capper-Volstead Act, which permits producer cooperatives to collectively process, prepare for market, handle, and market their products.

Adverse treatment at the hands of a regulated entity based on a grower exercising their right to join such an organization, including a cooperative or an association, is the exact conduct this provision addresses. However, the prohibition of regulated entities prejudicing a cooperative focuses on the cooperative's market interactions with the regulated entity compared to entities that are not cooperatives, and not on the formation or association of the cooperative itself.

Collectively, members of cooperatives are better able to gain access to markets, leverage negotiating power when dealing with regulated entities, and meet volume demands based on their ability to pool outputs. The rule supports covered producers in using procompetitive cooperatives to their fullest extent. This rule aims to ensure equal treatment of covered producers by regulated entities, regardless of whether or not a grower has exercised its right to join a grower organization or association. For these reasons, AMS has not changed § 201.304(a) to include ''or other association of producers.''

AMS notes that many producer associations are designed to give their members certain benefits, including some ability to negotiate with regulated entities around certain outcomes in the market. However, cooperatives are the only group of agricultural producers with explicit ability to cooperate and contract collectively with regulated entities, which includes Federal antitrust law exemptions not enjoyed by other types of associations. Nonetheless, AMS notes the importance of covered producers forming associations that may offer benefits to their members outside of collective contracting. To that end, the final rule in § 201.304(b)(2)(iii) provides important new protections against retaliation for forming or joining an association.

D. Specific Actions Constituting Prejudice or Disadvantage (§ 201.304(a)(2))

AMS proposed a non-exhaustive list of prejudicial actions that the regulation would prohibit, including offering less favorable contract terms, refusing to deal, differential contract enforcement, and contract termination or non-renewal.

i. Appropriateness of Specific Prejudicial Acts in Proposed § 201.304(a)(2)

AMS requested comment on the appropriateness of the specific prejudicial acts in proposed § 201.304(a)(2), as well as whether it should include any other forms of prejudicial conduct.

a. Offering Contract Terms Less Favorable Than Those Generally or Ordinarily Offered

AMS requested comment on whether offering contract terms less favorable than those generally or ordinarily offered should be considered a specific prejudicial or disadvantageous action against covered producers.

Comment: A cattle industry trade association and an agricultural advocacy organization proposed amending the prohibition of offering contract terms ''less favorable than those generally or ordinarily offered'' to reflect the fact that little is known about terms contained in forward contracts. They noted that it is unclear if the terms of forward contracts should be considered ''generally or ordinarily offered'' because, for example, atypical bonuses can be offered to a select number of preferred feedlots. If these bonuses are rarely offered, they may fall outside of the scope of ''generally or ordinarily offered,'' but would still disadvantage the other feedlots (market vulnerable individuals) that do not receive them. The commenters suggested AMS should instead compare specific terms of individual purchase agreements or contracts to determine violations.

AMS Response: Given the unique contract types in the cattle industry, AMS recognizes that certain premiums, discounts, and bonuses may not be ''generally or ordinarily'' offered. In this final rule, AMS is preserving the ability of regulated entities to be flexible in the types of contracts they offer to producers, with different producers having different contracts based on the particular quality and type of service provided for in the contract. Whether terms are generally or ordinarily offered is specific to the facts and circumstances of each case, including in comparison to similarly situated producers—a clarification which the final rule establishes. ''Generally or ordinarily offered to similarly situated producers'' is a fact-specific inquiry which looks to the contracting practices of the regulated entity, including how the regulated entity contracts for similar products or services with similar producers. While the rule does not guarantee any producer any particular contract terms, AMS underscores that the purpose of the rule is to prevent an adverse action based upon an unlawful basis. A refusal to offer a contract term *based upon* the producer's race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, or marital status, or age would weigh heavily in any analysis, as it inherently implies that the regulated entity is in the market to contract with those terms by others in the market. Such a circumstance is different than refusing to offer a contract because the producer is unable to meet special contract requirements.

AMS recognizes the existence of information asymmetry between regulated entities and covered producers, including in relation to what contract terms are commonly offered or not. AMS notes the availability of other tools to address that challenge, including new initiatives such as AMS's Cattle Contract Library Pilot, which provides disclosure into contract terms offered by packers with greater than 5 percent of the national market share, including disclosure of any contract specifications on financing, risk-sharing, and profit-sharing.[185] AMS also operates a Swine Contract Library, which provides transparency into contract terms in the swine sector.[186] When in doubt, AMS encourages covered producers to contact PSD. AMS is making no changes to the regulation as

[184] 7 U.S.C. 2302(2).

[185] Final Rule, ''Cattle Contract Library Pilot Program,'' Agricultural Marketing Services, December 2022, 87 FR 74951. For more information, see also Agricultural Marketing Service, Cattle Contract Library Pilot, at *https://www.ams.usda.gov/market-news/livestock-poultry-grain/cattle-contracts-library* (last accessed Dec. 2023). Note, as of the date of publication of the Pilot in January 2023, no covered packers reported to AMS contract specifications with financing, risk-sharing, or profit-sharing.

[186] Agricultural Marketing Service, Swine Contract Library Information, at *https://www.ams.usda.gov/rules-regulations/packers-and-stockyards-act/regulated-entities/swine-contract-library* (last accessed Dec. 2023).

proposed in response to these comments.

b. Refusing To Deal

AMS requested comment on whether refusing to deal should be considered a specific prejudicial or disadvantageous action against covered producers.

Comment: A cattle industry trade association and an agricultural advocacy organization recommended including in the prohibition on ''refusing to deal'' instances where a producer who ordinarily markets their livestock in the cash market is denied a bid unless they enter a forward contract with the regulated entity.

AMS Response: AMS is aware that market concentration in the cattle industry has had a negative effect on negotiated cash markets and on the ranchers who choose to deal exclusively in those markets, but the impact of thinning cash livestock markets on the ability of producers to use cash markets and freely enter forward contracts with regulated entities is outside the scope of this rulemaking. AMS will further consider the commenters' recommendations in the context of other rulemaking initiatives such as rules focused on particular species of livestock and evidentiary patterns of abusive conduct. AMS is making no further changes to the regulation as proposed in response to these comments.

c. Other Comments on Appropriateness of Specific Prejudicial Acts

Comment: Two farmers unions and several organizations generally supported the appropriateness of the list of specific prejudicial acts, but also recommended adding the phrase ''including, but not limited to'' to provide flexibility in evaluating future acts of discrimination or prejudice. An academic institution also endorsed the non-exhaustive list of specific actions provided in this section, suggesting the listed actions would reduce uncertainty in the industry and make this section of the rule easier to enforce.

AMS Response: This rule is not intended to limit AMS's ability to enforce the Act. Instead, the rule aims to better define the Agency's enforcement authority so that enforcement actions are more successful. AMS agrees with the commenters that listing specific prohibited prejudicial acts will aid enforcement efforts. The agency also agrees that such a list is meant to be exemplary, not exhaustive. To this end, ''any other action that a reasonable covered producer would find materially adverse'' has been added to § 201.204(a)(2) to indicate that a variety of other adverse actions done on a prohibited basis against covered producers may violate this section. The facts and circumstances of each case will be assessed in light of these provisions when determining whether the conduct in question violates the Act.

Comment: A swine industry trade association said that the specific ''prejudicial or disadvantaging'' acts listed, as well as the proposed rule's intimation that the list is ''non-exhaustive,'' would result in a vague and overbroad definition of prejudicial conduct. The commenter argued that terms such as ''favorable'' and ''generally or ordinarily offered'' vary with market conditions over time and would have to be ironed out in courts through costly litigation.

AMS Response: AMS has adequately described the type of conduct prohibited under this rule by expressly stating that undue prejudice and unjust discrimination on specified prohibited bases constitutes a violation under the Act.

AMS addressed concerns of vagueness by further defining conduct that is prejudicial or disadvantageous to producers in the final rule (as described in section V—Changes from the Proposed Rule). In particular, AMS has made a number of changes to provide additional clarity, specificity, and certainty to market participants relating to the list of adverse actions set forth in § 201.304(a)(2). In response to the commenter's concern that ''generally or ordinarily offered'' is a concept that may vary with market conditions over time, AMS revised the regulation to state ''generally or ordinarily offered to *similarly situated covered producers.*'' Including this phrase in the final regulations provides more specificity with respect to the current market context in which the regulation would be applicable. Paragraph (a)(2)(vi) was added to limit the list to any other adverse action that a *reasonable* covered producer would find *materially adverse.* The final rule also adds two exceptions to the rule in new paragraph (a)(3), which provides further specificity to the rule by defining specific actions which are not considered prejudicial conduct under this rule.

Nevertheless, AMS reads the statutory term ''prejudicial'' to be a broad term, that covers all acts that cause harm to covered producers on a prohibited basis with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. While the term ''prejudicial'' encompasses a broad range of conduct, it is not vague. This rule does not prohibit all harms that may be inflicted on covered producers by regulated entities, rather, only those prejudicial acts related to livestock, meat and poultry that occur on a prohibited basis.

Comment: A cattle industry trade association said AMS should not prohibit the specific acts outlined in the rule because they are important tools that allow the free market to function. The commenter suggested that, while less favorable terms or contract terminations are unfavorable results for producers that experience them, they are important outcomes that incentivize producer innovation. If these specific acts are prohibited, the trade association argued, regulated entities would need to resort to ''vanilla'' standardized contracts that would degrade consumer outcomes and impair superior producers' profit opportunities.

AMS Response: AMS rejects the argument that discrimination on the basis of race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, age of the covered producer, or the covered producer's status as a cooperative, or retaliation is a free market value. Engaging in that unjust discriminatory conduct would exclude participants from the market, rather than encourage them.

Moreover, the members of the trade association were mistaken even with respect to the original proposal protecting market vulnerable individuals. Regulated entities are free to use contracting tools to develop incentives. But a tool used to unduly prejudice the vulnerable does not incentivize; it oppresses. Any other conclusion is contrary to the plain meaning of the Act. This rule aims to create an inclusive, fair, and equal environment for farmers and ranchers to conduct business by preventing instances of unjust discrimination and undue prejudice. The key concept here is that there shall be no discrimination on the protected bases regarding the offering of ''general and ordinary'' contract terms. AMS concludes that the benefits of protecting farmers and ranchers from plainly unjustly discriminatory treatment outweigh the hypothetical prediction that such regulations will hamper efficiency or innovation. Inclusive markets breed innovation and efficiencies; they do not undermine them.

ii. Additional Forms of Prejudicial Conduct To Include

AMS requested comment on whether the four specific prejudicial acts are appropriate as proposed, or whether there are other forms of prejudicial

conduct that should be specified. Where other specific conduct is identified, AMS sought examples of how these actions have been used to target market vulnerable individuals or cooperatives.

Comment: An academic or research institution proposed adding a new specific action that would encompass ''information disclosure.'' The commenter defined information disclosure as failing to provide information materially relevant to a producer's operation while providing that information to one or more other producers. The commenter highlighted information asymmetry as a major fairness issue in livestock markets and suggested such asymmetry can heighten monopsony or oligopsony conditions. The commenter also cited the former Grain Inspection, Packers and Stockyards Administration's (GIPSA's) inclusion of information asymmetry in a 2010 proposed rule (the 2010 GIPSA Rule),[187] which defined undue or unreasonable prejudice or disadvantage as ''whether information regarding acquiring, handling, processing, and quality of livestock is disclosed to all producers when it is disclosed to one or more producers.'' The commenter encouraged AMS to use similar language in its final rule.

AMS Response: AMS is concerned about the negative impact information asymmetry, and the subsequent lack of transparency, has on producers. Information asymmetry could very well be used as a means of unjust discrimination if regulated entities preference certain producers over others through the information they choose to disclose. Such selective disclosure of information could cause those producers from whom information was withheld by regulated entities to lose out economically to those producers that received the information.

In the final rule, AMS has added paragraph (a)(2)(vi) to address any other action that a reasonably covered producer would find materially adverse. If a covered producer can show they are materially harmed by information asymmetry, they will have a recourse under this rule. Additionally, the prejudicial act of differential contract performance or enforcement (§ 204(a)(2)(iii)) covers selective information disclosure in many circumstances. Withholding materially relevant information from a contractee that it previously made available to the contractee or which it makes generally or ordinarily available as part of its contract performance to other contractees is de facto differential contract performance or enforcement. A producer is likely to operate in a less-than-optimal manner regarding financial renumeration when the regulated entity it is contracting with has withheld materially relevant information that has been disclosed to other contractees. Such behavior will thus lead to differential contract performance or enforcement.

AMS has not adopted the wide-ranging proposal on information asymmetry from the 2010 GIPSA Rule because it could inhibit the ability for regulated entities to select trusted partners with whom to engage in more complex, value-added production that may require specialized cooperation and information sharing.

Addressing information asymmetry and improving transparency in interactions between covered producers and regulated entities is a focus of AMS and will continue to be a priority in rulemaking. AMS made no further changes to the provisions regarding undue prejudices in response to this comment.

iii. Different Types of Purchase Arrangements That Could Be Employed in a Prejudicial Manner

AMS sought comment on whether there are other types of purchase agreements (outside of those generally or ordinarily offered), such as forward contracts, formula contracts, AMAs, or cash market purchases, that could be used in a prejudicial manner. AMS requested identification of these types and examples of how they have been used to target vulnerable individuals or cooperatives.

Comment: Several commenters argued that AMAs are predatory and should be prohibited under any name. An agricultural advocacy organization said that market vulnerable individuals are often excluded from participating in these agreements and bear negative market consequences from this exclusion. The individuals suggested that a firm base price for covered producers should be established instead.

AMS Response: This rule prohibits regulated entities from denying covered producers access to the purchase or sale of livestock on equitable terms, including through AMAs, on account of one of the rule's protected bases. AMS does not take a position in this rule on whether AMAs on principle are unfair or anticompetitive as such concerns are outside the scope of this rule.[188] AMS made no further changes in responses to the comment.

iv. Include Other Differential Contract Terms

AMS requested comment on whether other differential contract terms not listed in the proposed rule should be included when defining contract terms that are less favorable than those generally or ordinarily offered.

Comment: A cattle industry trade association urged AMS to consider three additions to differential contract terms:

1. Bonuses offered to select producers, which would disadvantage other producers who do not receive bonuses.
2. ''Cost-sharing.''
3. ''Cost-plus contracts'' where a regulated entity agrees to pay all the costs associated with purchasing and growing livestock, which disadvantages producers who do not receive cost-plus contracts.

AMS Response: This rule addresses undue prejudices that can exclude covered producers from the marketplace. As such, the rule focuses on terms that a regulated entity offers which are *less favorable* to those *generally or ordinarily* offered. To the extent that a regulated entity generally, commonly, or ordinarily offers bonuses, cost-sharing, and cost-plus contracts, then the denial of those terms to covered producers on the grounds of belonging to a protected class is covered by this rule as forms of differential contract terms. It is not, however, AMS's experience that those terms are generally, commonly, or ordinarily offered to producers, and based on the reporting in AMS's Cattle Contracts Library Pilot, are rarely if ever offered.[189] The rule does not prevent regulated entities from offering preferences to some producers, in particular for reasons relating to their choices in types of business relationships or how they incentivize quality of products or services delivered to them. This rule does not take a position on whether bonuses, cost-sharing, and cost-plus contracts may give rise to concerns of unfairness, undue preferences, or other concerns that are outside the scope of this rule.

[187] Implementation of Regulations Required Under Title XI of the Food, Conservation and Energy Act of 2008; Conduct in Violation of the Act, 75 FR 35338, 35352, June 22, 2010.

[188] See, generally, *https://www.afpc.tamu.edu/research/publications/710/cattle.pdf.* However, see also: *https://www.antitrustinstitute.org/work-product/aai-senior-fellow-peter-carstensen-responds-to-economic-research-on-marketing-of-beef-cattle-says-it-fails-to-address-market-power-and-buying-methods/.*

[189] See Agricultural Marketing Service, Cattle Contract Library Pilot, available at *https://www.ams.usda.gov/market-news/livestock-poultry-grain/cattle-contracts-library* (2023).

Accordingly, AMS made no change in response to this comment.

v. Include the Action of Offering Less Favorable Price Terms, Contract Terms, and Other Less Favorable Treatment in the Course of Business Dealings

AMS requested comment on whether AMS should include among the prejudices the action of offering less favorable price terms, contract terms, and other less favorable treatment in the course of business dealings than those generally offered to similarly situated producers.

Comment: A plant worker said AMS should avoid evaluating less favorable price or contract terms because each contract is based on varying circumstances that will inevitably result in different prices or terms. The commenter suggested that evaluating differential terms for discrimination will hamper regulated entities and producers' ability to bargain or negotiate for appropriate contract terms.

AMS Response: AMS agrees that contract prices commonly reflect a range of differences in circumstances between the contracting parties. To the extent that those prices reflect differences in product quality or service being provided, including transportation and delivery, parties are free to set prices in contracts as they wish. This rule focuses on exclusion or adverse actions on only the enumerated prohibited bases. Accordingly, AMS made no changes to the rule based on the comment.

vi. Allowance for Offering Less Favorable Price Terms, Contract Terms, and Other Less Favorable Treatment in the Course of Business Dealings for Legitimate Business Reasons

AMS requested comment on whether an allowance be made for offering less favorable price or contract terms, or other less favorable treatment due to legitimate business reasons.

Comment: A cattle industry trade association and agricultural advocacy organizations argued that legitimate business reason defenses should not be allowed because it would weaken the Act's purpose and allow continued harm to producers. A swine industry trade association and an industry company argued that exceptions should be provided for legitimate business reasons, and that AMS should: (1) provide clear examples delineating between legitimate and illegitimate forms of differential treatments, and (2) provide clarity on whose burden it is to prove that an act meets the legitimate business reason exception. The company asserted that without such an exception there would be frivolous litigation where regulated entities would have to defend legitimate behavior such as canceling contracts with producers who are found to have animal welfare violations. A plant worker agreed that legitimate business exceptions should apply, and pointed to California employment law's affirmative defense, which serves as a complete defense if a policy alleged to cause a disparate impact is found to be efficient for the business.

Commenters expressed concern that the proposed rule did not define legitimate business justification. Commenters expressed concern that the proposed rule fails to provide the industry with specific exceptions or justifications for disparate treatment of producers, stating there are multiple reasons why different (less favorable) terms may be offered to certain producers and not others, and that these reasons are not insidious in nature but instead a result of market forces and other nondiscriminatory factors. Additionally, several poultry industry commenters noted that AMS suggests in the preamble a legitimate business reason may justify disparate treatment, yet it never explains what constitutes a legitimate business reason. Several poultry industry commenters provided examples of reasonable business decisions that would result in differential treatment and may violate the proposed rule as written despite their reasonableness. These commenters urged AMS to add regulatory text similar to that in § 201.211 to expressly protect reasonable business conduct and specify how a company would demonstrate that an action was based on a reasonable business decision. The commenters also said that, due to the complicated nature of business relationships, business decisions should be presumed reasonable unless proven otherwise. A poultry industry trade association provided examples of complex fact patterns and asked, given each situation, how the regulated entity could demonstrate actions were taken for appropriate reasons.

An industry association contended proposed § 201.304(a) would eliminate the statutory requirement in 7 U.S.C. 192 that adverse actions against a market vulnerable individual are only prohibited if they are undue or unreasonable. The commenter noted the statute only prohibits ''undue or unreasonable'' advantages and disadvantages, meaning advantages or disadvantages that lack a reasonable business purpose. However, the commenter pointed out that, under the proposed rule, if the action is ''adverse'' and it impacts a market vulnerable individual, even if it was based on a legitimate business reason, the regulated entity would be in violation of the regulations. The commenter also noted that enforcing contract rights is often ''adverse against'' the other party, but ''adverse'' does not mean inappropriate or unfair. Commenters cautioned the proposed rule may result in regulated entities giving all producers the same contract terms to avoid litigation, which would eliminate the market competition the Act was intended to protect.

AMS Response: AMS agrees with commenters that legitimate business justifications exist for disparate treatment of producers. AMS does not agree, however, that there are many legitimate business justifications for prejudice or disadvantage on the basis of race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, or marital status, or age of the covered producer. The rule seeks to prevent regulated entities from discriminating against producers on specific prohibited bases, retaliating against producers for exercising certain protected rights, and deceiving producers in the procurement of livestock. It does not limit the ability of regulated entities to make other business decisions, as long as they comply with the Act in that they are not unduly prejudicial or unjustly discriminatory. This includes terminating contracts for violating contractual provisions such as animal welfare policies. To clarify what types of conduct are allowed, the final rule delineates two specific legitimate justifications for discriminatory action by regulated entities against producers. Discriminatory conduct by a regulated entity falling in one of these categories is not prejudicial: (1) the regulated entity is fulfilling a religious commitment related to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry, and (2) a Federally-recognized Tribe, including its wholly or majority-owned entities, corporations, or Tribal organizations, that is performing Tribal governmental functions.

AMS is adopting the religious exception to recognize the important role ritual slaughter plays in certain religious traditions. AMS is also recognizing the important roles that Tribes play as governmental units and operators of economic enterprises. In those governmental activities, as interpreted by the Supreme Court as well as Federal laws governing Tribal affairs, Tribes may require the flexibility to only purchase livestock from or sell meat to their members. AMS believes that actions following these two

principles do not amount to undue or unreasonable prejudice, disadvantage, inhibition of market access, or adverse action. Through its review of public comments and based on its experience, AMS finds these are the only two appropriate exemptions from the rule's broad prohibition against undue and unreasonable prejudices and disadvantages.

AMS underscores that, in this rule, legitimate justification only applies to whether adverse actions against covered producers on a prohibited basis are still permissible. Where the adverse action is *not* on a prohibited basis or was not differential in its treatment of producers on the prohibited basis, then the question of there being a legitimate justification is not relevant.

AMS disagrees with the comment that § 201.304(a) would eliminate the statutory requirement that a prohibited prejudice, disadvantage, or discrimination is undue, unreasonable, or unjust. To the contrary, AMS finds that prejudice, disadvantage, or discrimination on the prohibited bases set forth in this final rule to be per se unjust, undue, and unreasonable. As commenters to this rule have acknowledged prejudicial treatment on the prohibited bases has no place in the market.

E. Retaliation (§ 201.304(b))

AMS proposed addressing retaliation by outlining protected activities that a covered producer may engage in but that a regulated entity may not use as grounds for unjust discrimination or undue prejudice or disadvantage. The proposed regulations would have prohibited regulated entities from retaliating against covered producers for participating in a protected activity by terminating contracts, adversely differential performance or enforcement of a contract, refusing to renew contracts, offering more unfavorable contract terms than those generally or ordinarily offered, refusing to deal, interfering with third-party contracts, or other actions with adverse impact to covered producers. These proposed regulations are adopted in this final rule.

i. Usefulness of Regulatory Protections To Protect Producers From Retaliation

AMS requested comment on whether the proposed prohibition on retaliation would assist producers in avoiding unjust market discrimination, accessing markets, obtaining meaningful price discovery, or preventing anticompetitive practices.

Comment: Several organizations and an academic institution expressed support for the proposed rule's retaliation provisions, saying that poultry and meat companies take advantage of unbalanced power to create a climate in which farmers and ranchers fear retaliation for exposing unfair industry practices. One organization cited a recent anonymous survey of contract growers it had conducted, in which multiple respondents described experiencing retaliation from integrators and said integrators regularly terminate the contracts of farmers who engage in whistleblowing activities, leaving them with substantial debt tied up in specialized, single-use structures built as a condition of their contractual agreements.

An agricultural advocacy organization said § 201.304(b) as proposed fits easily within the scope of the Act's prohibitions on undue prejudice and unjust discrimination, closes a key enforcement gap, and represents a solid first step toward prohibiting unfair retaliation. An agricultural and environmental organization expressed support for the proposed provision but urged AMS to strengthen the final version. The commenter said regulated entities have deeply embedded retaliation into their business practices, leaving producers too intimidated to expose industry abuses. The commenter also cautioned that meat processors and live poultry dealers may attempt to find novel ways to retaliate against producers that do not directly violate the proposed rule, suggesting AMS broaden the range of protected producer activities and of prohibited retaliatory behavior.

A poultry grower expressed support for the protections, saying integrators had taken measures, such as delivering poor inputs and imposing extended timeouts on flock placements, against him and other growers who spoke up against abusive integrator practices. This commenter also said cattle and pork producers take similar actions against producers who expose problematic practices. A meat industry trade association said the proposed rule would ensure that farmers and ranchers have access to a public forum necessary for open, transparent communication. Numerous individuals indicated support for the proposed rule's protections against retaliation, with many saying the proposed rule would allow farmers to engage in whistleblowing actions without facing repercussions and would thus promote consumer, environmental, and animal welfare concerns.

AMS Response: AMS takes note of the commenters' support for the usefulness of the provisions. AMS designed the provision on retaliation to cover the core activities of being a producer—that is, activities are essential or unavoidable for producers in terms of their abilities to enjoy the full extent of their bargain and protect their economic rights. AMS notes that the provision that protects a covered producer who communicates or cooperates ''with a person for the purposes of improving production or marketing of livestock or poultry'' is broad. This covers many different scenarios not specifically named in this rule. AMS expects the retaliation provision of this rule to provide a significant measure of protection to covered producers against prohibited conduct, and likewise provide opportunity for redress, both to stop particularized harmful conduct, and keep it from persisting and causing greater harm. AMS chose this list of prohibited retaliatory practices based on conduct the agency identified as most commonly relevant to regulated entities' practices that exclude or penalize producers. This list is based on AMS's experience fielding complaints from producers, from its expertise in the operation of the livestock and poultry markets and practices of market participants, as well as the numerous comments to this rule that identified similar practices. AMS acknowledges there may be other forms of retaliation that would violate the Act that are not specifically delineated under this rulemaking. Prosecutorial discretion will determine what conduct is in fact retaliatory based on the facts and circumstances of each case. AMS made no further changes in response to these comments.

Comment: An agricultural advocacy organization suggested AMS consider further developing the enforcement procedures for the retaliation provisions, as well as the evidentiary burdens associated with complainants and defendants. The commenter specifically recommended that AMS establish a burden-shifting approach which would establish that, once a complainant has made a *prima facie* showing that a covered producer was subjected to retaliation after engaging in protected activities, the regulated entity would have to show by clear and convincing evidence that they would have taken the same action in the absence of the producer's participation in protected activities. Shifting the burden to the regulated entity (who has the best access to proof about the underlying facts) once the complainant has met an initial threshold would reflect a public policy position against

retaliation. The commenter said this approach would track with that used in other Federal whistleblower protection regimes, such as the Criminal Antitrust Anti-Retaliation Act [190] and the Whistleblower Protection Act applicable to the Federal civil service,[191] and would draw on a key element of Title VII discrimination law that allows complainants to initiate proceedings without being forced to prove the respondents' state of mind.[192]

AMS Response: As described in Section V—Changes from the Proposed Rule, subsection D—Retaliation Provisions, AMS changed ''because of'' to ''based upon.'' Paragraph (b)(1)'s prohibition as ''based upon'' is intended to be broader than ''but for'' causation and so capture when the protected characteristics or status are a material, or non-trivial, element of the decision to take an adverse action against a covered producer. AMS expects that fact-finding tribunals will establish the necessary processes for proving these elements. Moreover, AMS expects that evidentiary presentation may often follow those approaches to proving retaliation in other contexts as a function of the natural course of any litigation. AMS underscores that the rule is designed to protect producers' ability to engage in such covered activities, with the clarity provided by the rule specifically designed to assist producers in identifying and acting in a manner to effectuate their rights. AMS further notes that the prohibition on adverse actions taken on pretext are prohibited under 9 CFR 201.306 as established by this rule.

Comment: An organization said the proposed anti-retaliation provisions should cover violation disclosures made within the chain of command or as part of the producer's job duties because farmers and ranchers often report issues internally as a first step in drawing attention to them before reporting them to regulators or going public with them.

AMS Response: The rule as written protects covered producers from retaliation for protected activities, which include the assertion of contractual rights. Violation disclosures made within the chain of command or as part of the covered producer's contractual duties fall within the operation of the contract between the covered producer and the regulated entity, and as such may be expected to be covered by the rule. Accordingly, AMS made no change to the rule.

Comment: Several industry trade associations said the retaliation provisions are not necessary because the ''conduct'' at issue is already prohibited by existing laws, such as 9 CFR 201.211 identifying the criteria used to determine whether an action is an undue or unreasonable preference or advantage.

AMS Response: AMS agrees with the commenters that the retaliatory conduct at issue is prohibited under the Act and could be enforceable under existing rules and regulations, including criteria set forth in 9 CFR 201.211.[193] Compared to general criteria and interpretive guidance, this rule provides greater clarity, specificity, and certainty to how the Act applies, which will facilitate higher levels of compliance by regulated entities with the Act, broader enforcement of its provisions by AMS, and more informed producers, who will be in a better position to assert their rights established by the Act. Additionally, unlike § 201.211, this rule focuses on preventing undue prejudices and disadvantages and does not focus on preferential treatment that is not discriminatory. Accordingly, AMS made no change to the rule.

ii. Appropriateness of Specific Acts of Retaliation Listed in Proposed § 201.304(b)(3)

AMS requested comment on whether the specific retaliation acts listed in the proposed rule are appropriate. AMS also sought comment on whether there are other forms of retaliatory conduct that should be specified.

a. Termination or Non-Renewal of Contracts

AMS requested comment on whether termination or non-renewal of contracts is appropriate as a specific retaliation act listed in the proposed rule. It noted that covered producers have expressed fear of this type of retaliation through communication with AMS personnel and in comments on previous related rulemakings.

Comment: Numerous individuals said they are concerned about the prospect of farmers losing their contracts and their livelihoods if they raise issues with their treatment by poultry and meat companies.

AMS Response: AMS takes note of the commenters' support for the usefulness of the provisions. AMS made a range of adjustments in the final rule to enhance the final rule's protections for covered producers.

b. Interference in Farm Real Estate Transactions or Contracts With Third Parties

AMS requested comment on whether interference in farm real estate transactions or contracts with third parties is appropriate as a specific retaliation act listed in the proposed rule.

Comment: A swine industry trade association said the proposed rule describes the retaliatory conduct too vaguely, making it difficult for a regulated entity to determine whether its actions would be prohibited.

AMS Response: AMS believes that some degree of generality is necessary to capture the range of conduct that could give rise to a violation of the rule. However, the rule is not designed to prohibit every instance where a regulated entity's contracting decisions are unfavorable to a covered producer. For example, the rule would not apply where a regulated entity was engaged in unrelated business around the purchase or sale of farmland, or where a regulated entity chose for unrelated reasons not to continue a contract in the course of a covered producer's attempts to sell its farm. AMS believes that the wording of proposed § 201.304(b)(3)(iv)—''[i]nterference in farm sale transactions or contracts with third parties''—is appropriately specific to prohibit regulated entities from *retaliating* against covered producers for engaging in protected activities. This is because the focus of an AMS inquiry would be to determine the reason for the interference. AMS would determine whether a regulated entity interfered in a farm sale or third party contracting; if such interference occurred, whether it was harmful to the covered producer; and whether the interference occurred because the covered producer engaged in protected activity. Additionally, in response to this comment, AMS has included explanatory language in the retaliation section (Section VI.C—Provisions of the Final Rule, Retaliation) discussing the adverse effects that interference with the transfer of farm real estate by a regulated entity has on producers.

iii. Delineation of Additional Forms of Retaliatory Conduct

AMS requested comment on whether the specific acts of retaliation in the proposed rule are appropriate, and whether there are other forms of retaliatory conduct that should be specified.

[190] *See* 15 U.S.C. 7a–3(b)(2)(C).

[191] *See* 5 U.S.C. 1221(e)(2).

[192] *See, e.g., Young* v. *United Parcel Service, Inc.,* 575 U.S. 206, 206–07, 228–30 (2015)

[193] USDA, Agricultural Marketing Service, ''Frequently Asked Questions on the Enforcement of Undue and Unreasonable Preferences under the Packers and Stockyards Act,'' August 2021, *https://www.ams.usda.gov/rules-regulations/packers-and-stockyards-act/faq.*

Comment: Several commenters, including a farmers' union, a group of State attorneys general, and several other organizations urged AMS to explicitly state that the list of specific prohibited acts of retaliation is not meant to be exhaustive, with several commenters suggesting AMS add the phrase ''including, but not limited to'' to the introductory clause of § 201.304(b)(3). Commenters said establishing that prohibited activities are not limited to those listed would allow for future flexibility in addressing specific acts of retaliation that may arise.

AMS Response: As explained in Section V—Changes from the Proposed Rule, subsection D—Retaliation Provisions, in response to these comments, AMS has added a new paragraph (b)(3)(vi) to prohibit ''any other action that a reasonable covered producer would find materially adverse.''

Comment: A non-profit or other organization said the final rule should prohibit regulated entities from retaliating against any covered producers for any form of association, broadly defined, because allowing farmers to freely associate and to use a range of different communications platforms is necessary for the sector to flourish. An organization said the final rule should prohibit the offering of contract terms that are less favorable than those generally or ordinarily offered.

AMS Response: Proposed § 201.204(b)(2)(iii) provided broad protection against retaliation for a producer to form or join a producer or grower association and would cover all aspects of associations and cooperatives relevant to the business of livestock and poultry. Further, AMS acknowledges the importance of the freedom of association generally but underscores that the protections of the Act have limits. The Act is designed to protect covered producers in the business of livestock and poultry. AMS is not in a position to know or evaluate the full range of associations that individuals who are producers may join, and it would not be appropriate for AMS to be involved in encouraging or discouraging such associational activities, including whether regulated entities should be required to do business with covered producers that engage in those activities. Some associational activities unrelated to the business of livestock and poultry may expose regulated entities to reputational or other risks in the marketplace.

Comment: An academic institution recommended that AMS include language making it clear that the prohibited retaliatory activities would encompass coercion or intimidation, such as threats to take one of the prohibited actions.

AMS Response: This rule is intended to establish broad prohibitions against retaliatory activities that in AMS's experience have significantly inhibited producers' ability to freely compete and secure the full value of their products and services. AMS agrees that intimidation or coercion that would dissuade or coerce covered producers from engaging in the prohibited activities are covered under ''retaliate or otherwise take an adverse action against a covered producer.'' In particular, intimidating or coercive conduct that credibly threatens retaliation prohibited by this rule would rise to the level of actionable adverse conduct under by this rule—which the Agency underscores further through its addition of Paragraph (b)(3)(iii) and (v) under the list of adverse actions. For example, if a regulated entity were to communicate to a producer stating, ''if we were you, we would not report to the government'' with the implication that the regulated entity might not renew their contract on favorable terms, AMS views this as a form of prohibited retaliatory conduct in its incipiency that this rule is intended to stop.

iv. Protection of Producers Who Choose Not To Participate in Protected Activities

AMS requested comment on whether prohibitions on retaliation should protect producers who choose not to participate in protected activities. AMS provided the example of whether the provision should prohibit giving premiums or discounts for joining or not joining livestock or poultry associations.

Comment: A cattle industry trade association said these prohibitions should expressly protect producers from coercive conduct that directs them to either join or not join a particular producer association. An agricultural advocacy organization said the retaliation provisions should cover circumstances in which regulated entities reward producers who do not join a producer association. An agricultural advocacy organization noted that the freedom to refrain from associating is as important as the freedom to associate and represents the other side of the same coin.

AMS Response: AMS agrees that protected activities include the decision not to participate in such an activity. Based on its experience regulating the livestock sector, covered producers may be coerced by regulated entities to participate in associational activities or contact the government on regulatory and policy matters even when they may not agree. As recently as AMS's proposal on ''Transparency in Poultry Growing Contracts and Tournaments,'' covered producers reported to AMS potentially coercive pressure by regulated entities on poultry growers to oppose the regulation. AMS also notes commenter statements that regulated entities have pressured and may continue to pressure covered producers to join associations to support industry stances with which they disagree. Accordingly, AMS has added § 201.304(b)(2)(ii) and revised § 201.304(b)(2)(iii) to clarify that the decision not to participate in the protected activities, respectively, of engaging in a voluntary communication with the government or of forming or joining an association are also covered by the rule's protections against retaliation.

v. Appropriateness of Bases of Protected Activities

AMS requested comment on whether the bases of protected activities were appropriate, including the criteria for selection and application of those criteria. It further sought comment on whether the bases of protected activities are too broad, are too narrow, or should be changed in any other way. Comments received in response to this general inquiry are outlined below.

a. Communication With a Government Agency With Respect to Matters Related to Livestock, Meats, or Live Poultry or Petitions for Redress of Grievances

Comment: AMS requested comment on whether communication with a government agency on matters related to livestock, meats, or live poultry or petitions for redress of grievances is appropriate to include as a protected activity under § 201.304(b)(2).

Several agricultural advocacy organizations said AMS should make clear that the proposed rule would protect producer communication with any sector or level of government by including all three branches of government in this provision, with one commenter also recommending AMS specify this provision applies to both State and Federal government.

Several commenters recommended revised text as follows:

''(i) A covered producer communicates with a government agency, *court, or legislature* with respect to any matter related to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry or petitions for redress of

grievances before a court, legislature, or government agency.''

AMS Response: AMS agrees with the commenter and intends that the rule should include protections for communications with any of those entities, including any committee or member official of those entities. In this final rule, AMS is aligning the use of the terms ''government agency, court, or legislature'' and simplifying the language to ''government entity or official.'' This change ensures that protected communications may occur with any of the three branches of governments and with individual government officials, including committees and members of a legislature. As proposed, the rule did not limit its protection to communication with the Federal government. By using the words ''government entity or official,'' the rule's plain language applies equally to communications with all levels of government—Federal, State, Tribal, and local—with respect to the matters indicated.

b. Assertion of Rights Granted Under the Act, 9 CFR Part 201, or Contract Rights

AMS requested comment on whether assertion of rights granted under the Act, 9 CFR part 201, or contract rights is appropriate to include as a protected activity under § 201.304(b)(2).

Comment: A group of State attorneys general said the proposed rule may inadvertently leave out protections for farmers who communicate their concerns directly to regulated entities, suggesting AMS target this gap by expanding § 201.304(b)(2)(vii) (§ 201.304(b)(2)(ii) in the proposed rule) to include notification by a producer to the regulated entity of a potential breach of contract. An academic institution said protected activities should include the assertion of any civil right held by the producer, to the full extent feasible within the scope of AMS's authority. The attorneys general said that, while the proposed rule covers rights granted under the Act, the proposed rule, and contract rights, it does not encompass other rights a producer may have, such as whistleblower or other rights conferred by Federal or State law. An organization said the proposed rule should clarify, given the imbalance of power in contracting, that producers cannot waive the rights covered by this provision by any agreement, policy form, or condition of employment, including by a pre-dispute arbitration agreement.

AMS Response: With respect to the suggestion that AMS revise § 201.304(b)(2)(vii) to include notification by a producer to the regulated entity of a potential breach of contract, the regulation as proposed protects producers' right to assert their contract rights, their rights under 9 CFR 201, and their rights under the Act. The language of this protection necessarily encompasses the act of communicating with regulated entities, including to prevent a potential breach of contract; otherwise, a producer would be unable to exercise their contract rights. Accordingly, there is no need to add further notifications by the producer to the regulated entities to the list of protected activities in § 201.304(b)(2).

With respect to the assertion of any civil right, the protected activities enumerated in § 201.304(b)(2) were chosen because of their nexus to the business relationship between regulated entities and covered producers with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. To the extent that a contract between a regulated entity and a covered producer includes representations and warranties, including implied ones, relating to either party's compliance with other Federal or State laws, such as labor, health, and safety practices, this provision would extend to communications relating thereto. AMS notes that the protection afforded in § 201.304(b)(2)(vi) covers supporting or participating as a witness in any proceeding with the regulated entity. The rule does not change any additional protections that may be provided under other Federal or State anti-retaliation laws.

With respect to the request that AMS revise the rule to clarify that producers cannot waive rights covered by the rule, AMS believes that the commentors are mistaken about the structure of the Act and its regulations. AMS enforces this rule. Irrespective of any agreement between the contracting parties, AMS does not waive its responsibilities to enforce the Act. The Act and regulatory scheme are designed to vindicate the public interest in fair and honest markets. Thus, AMS regularly brings its own enforcement actions to sanction companies that violate the provisions of the Act, irrespective of the contracting parties' waivers of liability. A regulated entity that seeks a waiver from a producer through undue prejudice, retaliation or deception still violates the general provisions of the Act by using a deceptive, unfair, or unjustly discriminatory practice.

To the extent that individuals waive their rights, AMS points the commenter to existing regulations at 9 CFR 201.218, which limit the use of mandatory arbitration clauses, as mandated by Congress in the 2008 Farm Bill (Pub. L. 110–246). Specifically, those regulations require that the regulated entity offer the producer or grower a specific disclosure regarding the ability to decline a mandatory arbitration clause and indicate that failure to accept or decline the arbitration clause will be treated as if the clause is declined. Additionally, the regulation sets out criteria governing the reasonableness of the arbitration clause. Arbitration is a procedural forum that some parties may utilize to adjudicate substantive rights; arbitration clauses cannot waive substantive rights under contracts or the Act.

Accordingly, AMS is making no changes to the rule in response to these comments.

Comment: A swine industry trade association said the broad language of this provision could be read to mean that the proposed rule extends to the point that carrying out the terms of a contract is considered a protected activity.

AMS Response: AMS agrees with the comment. The assertion of rights under a contract includes the covered producer's ability to assert contract performance. Accordingly, AMS is making no changes to the rule in response to this comment. However, as the commenter notes, asserting rights under a contract is not a protected activity under the Act and it is not the intention of AMS to incorrectly assert this false presumption through this rulemaking.

c. Assertion of Right To Form or Join a Producer Association or Collectively Process, Prepare for Market, Handle, or Market Livestock or Poultry

AMS requested comment on whether assertion of the right to form or join a producer association or collectively process, prepare for market, handle, or market livestock or poultry is appropriate to include as a protected activity under § 201.304(b)(2).

Comment: An academic institution said the proposed rule should extend its protection of communications associated with asserting the rights named in proposed § 201.304(b)(2)(iii) to also cover producers engaging in talks about these activities. The commenter said this change would ensure that retaliation protections clearly include the initial communications and negotiation process for producers taking steps to form or join a producer association or collectively process, prepare for market, handle, or market livestock or poultry.

A whistleblower advocacy organization said it supported the

proposed rule's protection of the right to associate because retaliation would limit producers' ability to exchange information and engage in pro-competitive collaboration.

Multiple individuals said participation in producer organizations and associations helps provide farmers with more access to information relevant to their businesses and promotes competition by enabling the production of better-quality products. A former trade association CEO said the social and informational benefits of association membership are especially important in the farming industry because of its potential for isolation. This commenter further suggested large agricultural companies would do well to appreciate the benefits of producer participation in such organizations, such as opportunities to make progress on solving problems, develop industry consensuses for presenting to government, and hear the perspectives of members with opposing views. An individual said producer organizations often act as a barrier between individual producers and consumers, and the proposed rule would prevent producer organizations from retaliating against producers who try to change this behavior and provide truthful information about the conditions under which their products are grown or raised. The commenter said this would protect farmers' right to organize to improve their pay and working conditions.

AMS Response: AMS believes that the act of forming or joining an association clearly encompasses the act of communicating about the formation or joining, including examining the decision whether to form or join an association. All such activities are covered by the final rule. Therefore, AMS does not make any changes to the rule on those grounds.

Additionally, AMS appreciates that producer organizations may at times be at odds with their producer members. However, producer organizations are not considered regulated entities under this rulemaking, and thus retaliatory conduct at the hands of such organizations is not covered. Producers have the choice to join or separate from such organizations based on their individual feelings surrounding the costs and benefits such membership brings. If producers feel as though their membership of an organization is serving as a barrier between them and consumers, thus preventing transparency regarding growing conditions, producers may find it advantageous to disassociate. Often producers do not have this luxury in their relationship with packers and integrators due to their reliance on these regulated entities and the absence of alternative buyers due to regional concentration.

Comment: A swine industry trade association said § 201.304(b)(2)(iii) is overly broad, arguing that any covered producer that joins an industry association or seeks to do so would then have the means—based on that membership—to make a claim against a regulated entity for engaging in perceived retaliatory behavior.

AMS Response: AMS disagrees with the commenter's assertion. The regulation protects the covered producer from retaliation for forming or joining an association or choosing not to join an association. It does not protect the covered producer from other acts that the association may take. This rule does not condone, for example, associational behaviors that violate the Sherman Act. Nor does this rule otherwise restrict the relationship between regulated entities and covered producers, whether the association may support or condemn particular acts or practices. Nor, additionally, does it suggest that the mere fact of forming or joining an association garner absolute protection from adverse actions by the regulated entity which are unrelated to forming or joining an association. Therefore, AMS has made no changes to the regulation as proposed.

d. Communication or Cooperation for Purposes of Improving Production or Marketing of Livestock or Poultry

AMS requested comment on whether communication or cooperation for purposes of improving production or marketing of livestock or poultry is appropriate to include as a protected activity under § 201.304(b)(2).

Comment: A swine industry trade association said this provision is too broad because it could be read to mean that many communications related to a producer's business are protected.

AMS Response: AMS fully intends to protect many of the communications a producer makes in the ordinary course of business, so that the producer may freely operate in the market without fear of retaliation. Therefore, the regulation protects lawful communications and cannot, and does not seek to, absolve covered producers from unlawful communications. Section 201.304(b)(2) makes this clear by underscoring that the producers' activities are protected from retaliation only to the extent they are not otherwise in violation of Federal antitrust and other relevant laws. Furthermore, to find a violation of § 201.304(b)(2) there must be a causal connection between the regulated entity's behavior and a producer's protected communications, including where a regulated entity makes a threat that would reasonably dissuade the covered producer from engaging in the protected activity. AMS made no changes in response to this comment.

e. Supporting or Participating as a Witness in any Proceeding Under the Act or a Proceeding Relating to an Alleged Violation of Law by a Regulated Entity

AMS requested comment on whether supporting or participating as a witness in any proceeding under the Act or a proceeding relating to an alleged violation of law by a regulated entity is appropriate to include as a protected activity under § 201.304(b)(2).

Comment: An organization and several individuals indicated support for this protection, saying the ability to testify without fear of retaliation is crucial for promotion of fair and competitive livestock and poultry markets. Some of these commenters mentioned the example of cattle ranchers who declined to testify before Congress after facing threats and retaliation. The organization urged AMS to extend this protection to participation, assistance with, or intent to participate in any investigation of a possible violation of the Act.

AMS Response: The regulation already extends this far. The proposed regulation protected any communication with a governmental entity, including a governmental agency, legislature, or court, with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. This protection encompasses participation, assistance, or intent to participate in any investigation of a possible violation of the Act. AMS provided an additional protection with respect to serving as a witness because of the different and more public nature of such communication. Furthermore, to underscore the importance of respecting the independent functioning of the judicial process, the provision covers the covered producer's ability to serve as a witness in any proceeding against a regulated entity. AMS made no changes in response to this comment.

f. Other Comments on Appropriateness of Bases of Protected Activities

Comment: A number of commenters urged AMS to expand the list of protected activities. An agricultural and environmental organization said AMS should disavow the proposed rule's position that adverse activities not tied

to the proposed list of protected activities would not receive protection under the rule, arguing that retaliation of any kind against producers exercising their lawful rights qualifies as unjust discrimination and an unreasonable prejudice under the plain meaning of the Act. The commenter urged AMS to instead include the following catch-all provision to protect covered producers from retaliation against other lawful conduct in service of livestock production and marketing:

''(viii) A covered producer engages in any lawful conduct for the purpose of improving production or marketing of livestock or poultry.''

A farmers union said AMS should broaden the grievance-sharing activities producers can participate in to give producers more protection from retaliation.

An agricultural advocacy organization said AMS should protect the ability of producers to freely associate with other farmers and other organizations, including using social media or other communication platforms.

An agricultural and environmental organization said AMS should expand the list of protected activities to include situations in which producers maintain their status as independent participants on open markets, refusing to enter into forward contracts or other contractual agreements that set future price or performance at the regulated entity's request. According to the commenter, producers who resist entering into forward contracts and AMAs often face retaliation, and therefore the final rule should protect them. The commenter recommended AMS add another paragraph to § 201.304(b)(2) as follows:

(vii) A covered producer refuses to sell livestock or poultry through forward contracts, AMAs, or similar contractual arrangements, opting instead to engage in open market sales.

An organization said lawful communications protected under the proposed rule should also include situations where a complainant provides information regarding conduct that they reasonably believe violates the Act or is about to do so. The commenter said that, because most people are not experts on their rights under the Act, the proposed rule should establish that complainants do not need to mention specific violations and that, as with similar corporate anti-retaliation measures, they do not need more than a subjective, good faith belief that the conduct at issue violates the Act. The commenter also said AMS should allow these complaints in any language and by means including in person, in writing, and by email.

An academic institution said the protected activities listed in the proposed rule are all important in empowering producers to assert their rights and promote fair markets.

AMS Response: AMS appreciates and shares the commenters' viewpoint that retaliation is a serious concern in the livestock and poultry industry. AMS has attempted to craft this regulation to respond to the most common and clearly defined forms of retaliation in the form of prohibited unjust discrimination on the basis of protected activities. The regulation does not seek to define every prohibited activity, as the Act may limit unjust discrimination in circumstances not foreseen by this final rule. If covered producers believe they have suffered a form of unjust discrimination that is prohibited by the Act, they should report that to AMS.

AMS notes that communication with other producers for the purposes of improving the production or growing of livestock or poultry is already protected by the proposed regulation. Such communication may include sharing grievances over practices by regulated entities or others as such communications relates to covered producers' desire to overcome obstacles to improving or marketing their livestock or poultry.

AMS acknowledges a commenter's concern regarding some covered producers' interest in not utilizing forward contracting for the sale of livestock. However, regulating whether covered producers have a right to any particular form of livestock sales transaction is outside the scope of this rule.

AMS underscores that, to obtain the protection of this regulation, the producer need not engage in any particular form of the activity, such as quoting a precise regulatory section to assert an Act right. The focus will be on the substance of the producer's activities, and a good faith effort to assert an Act or contractual right is still protected from retaliation *on the basis of that assertion* regardless of the precision, imprecision, or even good faith inaccuracy of the legal or contractual right being asserted by the producer.

Accordingly, AMS did not make any changes in response to the comments.

vi. Limiting of Protected Activities Relating to Communication and Cooperation, Beyond Government Entities, to USDA Extension and USDA Supported Non-Profit Entities

AMS asked for input regarding whether protected activities related to communication and cooperation should be limited to USDA extension and USDA-supported non-profit entities, beyond government entities.

Comment: Several commenters supported expanded protections for activities related to communication and cooperation. An agricultural advocacy organization said AMS should not limit these protections to USDA extension and USDA supported non-profit entities because producers may have concerns about their industry that extend past the department's jurisdiction, giving examples such as concerns about managing animal waste that fall under State and Federal environmental regulations or issues relating to veterinary drugs or animal feed that are regulated by the Food and Drug Administration.

An academic or research institution and several organizations said, given the information asymmetry and lack of transparency in livestock and poultry production markets, AMS should extend protection to more types of communications that producers may want or need to pursue in preventing market exclusion and asserting their rights and protections. Commenters suggested AMS should protect producer social media posts about unfair integrator treatment, as well as producer communications with relevant third parties, such as lawyers and legal aid organizations, veterinarians and others doing work related to animal welfare, producer advocacy organizations, and the media.

Several commenters said AMS should introduce this provision in a new § 201.304(b)(2)(ii), with other commenters providing the following variations on recommended regulatory text:

(ii) A covered producer takes an action through a non-governmental third party that causes the producer's grievances against a regulated entity or a group of regulated entities to be known.

and

(ii) A covered producer communicates with a reporter, private investigator, public interest organization, or the general public through traditional media or social media with respect to any matters related to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry; so long as such communication does not expose a trade secret a regulated entity has reasonably and clearly identified in writing as a sensitive and confidential trade secret. A regulated entity's claim that any communicated information is a sensitive and confidential trade secret is not reasonable if the information is publicly available, shared by the regulated entity to any third party that is authorized to disseminate the information, or exposes standard industry practices common

among more than one regulated entity in the relevant market.

AMS Response: AMS takes note of the commenters' recommendations of expanded protections for activities related to communication and cooperation. AMS believes that the commentators' concerns are largely addressed in the rule, which protects lawful communications with government agencies or other persons for the purpose of improving the production or marketing of livestock or poultry, exploring a possible business relationship, or supporting proceedings under the Act against a regulated entity, among other protected activities. The regulatory text provides broad coverage for these activities in § 201.304(b)(2)(iv) through (vi), without limitation. These communications are protected because they enhance producers' ability to receive protection under existing laws, improve the production process, and facilitate enforcement of contracts in ensuring producers receive their bargain for exchange. Communications unrelated to those purposes are outside the scope of this regulation.

Whether social media communications are covered will depend on the protected activity in question and the particulars of the social media forum in question. Whether a public post by a covered producer about treatment by a regulated entity that the covered producer asserts to be in violation of the Act or is otherwise harmful to the producer may depend on the facts and circumstances of the post. For example, to the extent that the producer is testifying to Congress or courts regarding unfair treatment and the social media post simply refers to the testimony or describes the same material, then, for example, such a post would likely be protected, depending on the full scope of the facts and circumstances.

Similarly, if the social media post is part of an effort to share information with other producers for the improvement of production or marketing or is part of an effort to form an association or engage in cooperative activities, that would likely be protected under this rule as well since the rule is agnostic as to the form of the communications between producers. However, AMS notes that the activities protected under this rule are covered to the extent that these activities are not otherwise prohibited by Federal, State, or Tribal law. For example, the rule does not provide an exemption from defamation laws.

Nor does this rule attempt to preempt freedoms of the press. Whether a communication with a reporter or public investigation organization is covered will depend upon the facts and circumstances. The inquiry would need to balance the important role that freedom of the press plays in maintaining market integrity with legitimate expectations by a regulated entity of good faith behavior by a producer under a contract. Relevant questions include whether the communication was part of a factual effort to assist the reporter in understanding and reporting on asserted violations of law and regulation and whether the producer provided any confidential business information to the investigator or otherwise exposed the regulated entity to commercial risk or reputational damage unrelated to the violation in question. Also potentially relevant, in some circumstances, may be whether the producer has exhausted other avenues for resolving any dispute and also the extent to which the regulated entity has a reputation recognized in the market for retaliation which would otherwise place the producer in fear of asserting rights even with the presence of this rule.

The rule does not provide unlimited license for producers to damage the reputation of regulated entities. A social media post principally functioning as a threatening or coercive public communication is unlikely to be covered, absent other extenuating facts and circumstances. AMS underscores that the rule is intended to facilitate lawful communication and the exercise of lawful economic rights by covered producers, and the promotion of competitive markets and markets with integrity. That goal is most effectively served by enabling producers to exercise contractual and legal freedoms, communicate with government, other producers, and competitor firms for the purposes set forth in this rule. Therefore, AMS makes no changes to the rule in response to these comments.

vii. Sufficiency of Proposed Anti-Retaliation Provision's Protection Regardless of Covered Producer's Type of Business Organization

AMS requested comment on whether the proposed anti-retaliation provision provides sufficient protection for all types of covered producer business organizations.

Comment: An agricultural advocacy organization indicated that this provision provides sufficient protection regardless of the covered producer's type of business organization.

AMS Response: AMS made no changes in response to this comment.

viii. Extension of Protections for Exploring a Business Relationship to Such Activities With any Person, Rather Than Solely Regulated Entities

AMS requested comments on whether protections for exploring a business relationship with a regulated entity are sufficient, or whether such protections should extend to exploring business relationships with any person, in addition to regulated entities.

Comment: Several organizations asked AMS to broaden these protections to include communications and negotiations with any entity for the purpose of exploring a business relationship or alternative business model. According to these commenters, producers may want to explore alternative uses for industry livestock or poultry-raising infrastructure or add an additional type of agriculture to their operation. Several commenters said that while they recognize that producers who transition outside of the industry would no longer be covered under the Act or subject to many of the retaliatory actions covered by the proposed rule, they believe extending this protection is necessary so producers can fully explore all potential business opportunities without worrying about punishment if they do decide to retain their current business relationship.

Several commenters recommended the following revisions to § 201.304(b)(2)(v):

> (v) A covered producer communicates or negotiates with a regulated entity, other commercial entity, or relevant consultant for the purpose of exploring a business relationship or alternative use or application of their property.

AMS Response: The purpose of the provision is to preserve and promote the competitive position of the covered producer, and as such to ensure that the covered producer is not discouraged from seeking competitive alternatives by a regulated entity's retaliation. Paragraph (b)(2)(v) protects a covered producer's ability to communicate, negotiate, or contract with a regulated entity, another covered producer, another commercial entity, or consultant, for the purposes of exploring or entering into a business relationship. The Act is intended to ensure maximal competitive flexibility for covered producers. It may be the case that producers wish to explore a business opportunity by communicating, negotiating, or contracting with a consultant about forming a cooperative or, with a commercial intermediary such as an exchange or auction, or with another covered producer or commercial entity that may not yet be

a regulated entity but intends to engage in meat or poultry processing. It may also be the case that producers wish to negotiate with other covered producers for the purpose of jointly investing in a business venture such as a slaughter facility. Accordingly, AMS has amended the regulation to indicate that the final rule provides protection for a covered producer who communicates, negotiates, or contracts with a regulated entity, another commercial entity, another covered producer, or a relevant consultant, for the purpose of exploring a business relationship. AMS concludes that a consultant either works to benefit another commercial entity or works to benefit the covered producer, and so would be covered by the provision.

ix. Include Catch-All Clause in Proposed List of Regulatory Actions To Cover Offering of Less Favorable Contract Terms

AMS requested comment on whether the proposed list of retaliatory actions should include a catch-all clause, such as ''offering contract terms that are less favorable than those generally or ordinarily offered.''

Comment: Several organizations indicated support for a catch-all provision. The commenters said they would be in favor of prohibiting the retaliatory offering of less favorable contract terms as AMS suggested in the preamble to the proposed rule. Commenters said this addition would recognize the importance of contracts as a retaliatory weapon because of their effect on producers' financial well-being and would avoid a potential loophole for the proposed rule's prohibition on retaliatory termination or non-renewal of contracts and refusals to deal. One commenter suggested that AMS include a new provision saying ''offering unfavorable contract terms that otherwise affect reprisal'' or ''offering contract terms that are less favorable than those generally or ordinarily offered'' is a prohibited action. However, several commenters recommended that AMS also introduce a second, broader catch-all provision to ensure that regulated entities cannot simply formulate new ways to retaliate against producers for engaging in protected activities. These commenters suggested that AMS add the following regulatory text to § 201.304(b)(3) to achieve both aims:

(v) Offering unfavorable contract terms in contract formation, contract modification, or contract renewal that affect reprisal.

(vi) Any other action that adversely impacts a covered producer's financial or reputational interests or may result in diminished contract performance with the regulated entity.

Unfavorable contract terms include, but are not limited to: price terms, including any base or formula price; formulas used for premiums or discounts related to grade, yield, quality, or specific characteristics of the animals or meat; the duration of the commitment to purchase or to contract for the production of animals; transportation requirements; delivery location requirements; delivery date and time requirements; terms related to who determines date of delivery; the required number of animals to be delivered; layout periods in production contracts; financing, risk-sharing, and profit-sharing; or terms related to the companies' provision of inputs or services, grower compensation, or capital investment requirements under production contracts.

AMS Response: AMS elected not to introduce a provision prohibiting the ''offering of contract terms that are less favorable than those generally or ordinarily offered'' to its list of prohibited retaliatory actions as requested by a commenter because retaliation is principally focused on protecting producers from adverse actions by regulated entities in which they already have establish or recurring contractual relationships. The list of adverse actions in paragraph (b)(3) was designed to provide examples of the most common forms of retaliation as discrimination addressed by this rule. However, the proposed rule was intended and drafted broadly so as to ensure producers can engage in protected activities at all times and with all regulated entities in the marketplace. As described in Section V—Changes from the Proposed Rule, the final rule provides more specificity. Yet the final rule would still protect a producer against adverse treatment by a regulated entity which may be seeking to chill those activities across the marketplace—such as forming a producer association or asserting rights under the Act with other regulated entities—through the clarification that other actions that a reasonable covered producers would find materially adverse.

Additionally, AMS accepts the commenters' critique that the proposed regulatory text was insufficiently specific to provide clarity regarding when regulated entities could and could not take adverse actions against covered producers. In particular, AMS is concerned that the proposed contours regarding refusals to deal and non-renewals offer regulated entities too great a latitude to engage in retaliation, because a regulated entity could, in theory, satisfy the proposed rule by simply offering highly unfavorable terms to the covered producer—which it could not do if the agency prohibited ''offering of contract terms that are less favorable than those generally or ordinarily offered.'' That is not, however, the intent of the regulation. Rather, it is to ensure that covered producers, in whatever circumstance they enjoy, do not suffer retaliation for effectuating their rights under the Act.

Accordingly, in the final rule, AMS has amended the provision to add several clarifying details. First, the final rule clarifies that requiring modifications or only offering to renew contracts on terms less favorable than those enjoyed by the covered producer is a violation where it occurs because the covered producer engaged in protected activities. This provision covers any adverse change to the covered producer's terms to provide maximum flexibility to the covered producer to exercise protected rights regardless of the particular circumstances. Second, the final rule clarifies that a refusal to deal with covered producers would be triggered where the regulated entity fails to offer terms generally or ordinarily offered to other similarly situated covered producers. This provision does not guarantee the covered producer the most favorable contract terms in the market, but simply those that the covered producer would generally or ordinarily offer to other similarly situated covered producers that had not engaged in protected activities, which could include the situation previously enjoyed by the covered producer prior to having engaged in the protected activity. Such a provision is necessary because covered producers may enter or exit the market at different times, and during that period may engage in protected activities for which a regulated entity may attempt to retaliate. Together, AMS believes that these modifications cover the most common circumstances that covered producers may encounter in their business dealings in which regulated entities may attempt to exact retaliation.

AMS is not including the level of detail sought by some commenters regarding the specific form of retaliation. This rule is intended to provide protections for adverse actions against a covered producer based upon the protected activity (including threats intended to chill engaging in that activity). Any inquiry should focus on those bases, rather than on the particular form of the discriminatory harm. AMS recognizes that unfavorable

contractual terms can cover a wide range of elements of a contractual relationship, such as prices, formulas, premiums or discounts, transportation provisions, delivery dates, duration, the required number of animals, arrangements such as financing, investment requirements or incentives, and other contractual specifications, among other terms and conditions. Such unfavorable terms may have direct financial impacts but may also have indirect financial impacts, such as reputational impacts which adversely affect the covered producer's ability to conduct business in the marketplace. Providing further detail in the regulatory text is not necessary to enforce the rule. It is not practical to name all the different ways a malicious actor could find to retaliate. The rule is intended to capture as fully as possible the difference between a serious contract offer and an offer that has the practical intent to retaliate.

Additionally, AMS confirms that when a regulated entity claims that modification or renewal of a contract on less favorable terms is common with similarly situated producers for reasons unrelated to any exercise of protected activities, AMS will not automatically consider the less favorable modification or renewal a violation of this particular rule. AMS will, however, review modification and renewal and will carefully examine the regulated entity's justifications. Even outside of retaliation, unilateral modification of existing contracts has been a violation of the Act. The Act considers it an unfair and deceptive practice to modify an existing contract to either extend the time for payment or reduce the full price agreed upon at delivery. Moreover, contract modification has been a deceptive practice where the terms offered publicly were privately disavowed.

x. Include Other Contract Terms That Could Affect Reprisal

AMS requested comment on whether other contract terms should be included as part of including a non-exhaustive list of contract terms that could affect reprisal.

Comment: An organization said AMS should provide examples of adverse actions that could constitute retaliation to help regulated entities comply with the Act. The commenter said that, for example, adverse actions for speaking out might include negative performance reviews; denial of bonuses; harassment or assault; reduced input quality; or increased scrutiny. The commenter said the proposed rule should cover adverse actions in contract terms such as impacts on price terms; formulas used for premiums or discounts related to grade or other characteristics of the animals or meat; duration of commitment to purchase or contract for the production of animals; transportation or delivery requirements; or terms related to companies' provision of inputs or services, grower compensation, or capital investment requirements under production contracts.

AMS Response: AMS recognizes that unfavorable contractual terms can cover a wide range of elements of a contractual relationship, such as prices, formulas, premiums or discounts, transportation provisions, delivery dates, duration, the required number of animals, arrangements such as financing, investment requirements or incentives, and other contractual specifications, among other terms and conditions. Such unfavorable terms may have direct financial impacts but may also have indirect financial impacts, such as reputational impacts which adversely affect the covered producer's ability to conduct business in the marketplace. In the final rule, AMS has added paragraph (b)(3)(iv) to address any other adverse action that a reasonable covered producer would find materially adverse. This is intended to focus on material harms to covered producers, including threats, based on the protected activities. However, AMS is not including the level of detail sought by some commenters regarding the specific forms of retaliation, because providing further detail in the regulatory text is not necessary to enforce the rule. There are too many possibilities to encompass every possible retaliatory action in a single rulemaking. The Agency prefers the general prohibitions because their simplicity reaches a broad array of unlawful retaliatory activities, including the ones the commenter raises.

xi. Specific Challenges or Burdens Regulated Entities Might Face in Complying With Anti-Retaliation Provisions of Proposed Rule

AMS requested comment on what challenges or burdens regulated entities may face in complying with the proposed rule's anti-retaliation provisions.

Comment: Multiple industry groups argued the retaliation provisions are overly broad and vague, leading to compliance uncertainties and the threat of litigation.

A cattle industry trade association said that AMS's decision to allow violations of the proposed rule's retaliation provisions without demonstrating harm to competition, along with ambiguous definitions letting a wide range of parties qualify as potential complainants, puts the cattle industry in danger of a huge wave of lawsuits that could thwart innovation. A swine industry trade association said the prohibited forms of retaliation listed in § 201.304(b)(3) include a broad range of activities that a regulated entity may have legitimate business reasons to carry out. According to the commenter, these prohibitions would restrict the rights of regulated entities to freely deal and require them to treat every producer the same, putting the proposed rule in conflict with the Act and with antitrust law. A poultry industry trade association and several live poultry dealers said that the list of activities that constitute retaliation is not exhaustive, so regulated entities have no way to know what activities they must avoid to comply with the rule.

AMS Response: In this final rule, AMS has made a number of changes, outlined above in Section V—Changes from the Proposed Rule, to provide additional clarity, specificity, and certainty to market participants. These include switching prohibited conduct in § 201.304(b)(3) from an exemplary list to a specific list of covered items. AMS rejects the general assertion that the provisions on retaliation are vague, ambiguous, or non-exhaustive. To the contrary, the final rule sets forth specific activities that are protected (§ 201.304(b)(2)) and specific conduct (§ 201.304(b)(3)) that would constitute retaliation if it were done because of the producer engaging the protected activities. As described above under Section V—Changes from the Proposed Rule, these included a range of further clarifications to the specific conduct. Notably, the inexhaustive list under paragraph (b)(3) has been refined, with paragraph (b)(3)(v) added to limit the list to any other adverse action that a *reasonable* covered producer would find *materially adverse.*

The activities protected by this final rule each constitute an exercise of basic freedoms necessary and essential to maintain a free and competitive market—freedoms such as exercising contractual and legal rights, seeking recourse through governmental channels, forming cooperatives or associations relating to the business of livestock and poultry, and being a witness in court. Most regulated entities assert that retaliation for engaging in these types of activities is not a common practice in the industry. AMS finds that factually questionable, given the level of complaints and concerns expressed by producers over the years, including

experience in response to producers' participation in hearings on competition by USDA and the DOJ in 2010. But to the extent that regulated entities stand by that position, then there should be little risk to regulated entities from litigation on the grounds of the activities protected in this rule. Regardless, AMS can identify no competitive benefits to adverse actions against covered producers for engaging in the activities protected by this final rule and can identify no genuine risks to contractual freedoms or ability to legitimately innovate from the activities protected by this final rule.

AMS has further responded to the question of the costs and risks of litigation below.

Comment: A swine industry trade association said that the retaliation provisions provide no guidance on legitimate business reasons to engage in the activities deemed as retaliatory conduct or on whose shoulders the burden of proving that a regulated entity's conduct was ''because of'' the producer's activity rather than based on a legitimate reason. A poultry industry trade association and several live poultry dealers said the proposed rule also does not clarify how to establish that a live poultry dealer, and the specific employees involved in grower contracting, knew that a grower had engaged in one of the protected activities.

AMS Response: AMS has not identified any competitive benefits to adverse actions against covered producers for their having engaged in any of the protected activities set forth in this final rule. Accordingly, AMS has not provided any exemptions to the prohibition on retaliation against covered producers. If a regulated entity claims it has taken an adverse action against a covered producer for reasons unrelated to the producer's exercise of rights protected by this final rule, it becomes a factual question of proof. The agency has the burden of showing that the regulated entity violated the rule by taking covered adverse actions against a producer or grower wholly or in part because of the producer's or grower's exercise of a protected right under the rule. Any such determination will turn heavily on the particular facts and circumstances of any claim. This factual determination is not a question of whether a legitimate business reason existed to engage in the retaliation; rather it is a question of whether a violation occurred at all. In some cases, it may be possible that the regulated entity, including in the form of its agent interacting with the covered producer, is genuinely not aware of the protected activity by the covered producer (including not having constructive knowledge, being willfully blind, or grossly negligent in its affairs), the adverse action would not constitute a violation. AMS does not expect, and indeed does not encourage, the regulated entity to engage in any monitoring activities to attempt to make itself aware of when covered producers may be engaging in these activities. In fact, the purpose of the rule is the opposite, and were AMS to identify a regulated entity engaging in any such monitoring program, it would likely view such activities as being in violation of this regulation owing to their likely effect of intimidating producers.

Comment: A swine industry trade association said the proposed rule would allow producers who engage in common conduct, such as joining a cooperative or asserting their rights under a contract, to claim that a regulated entity engaged in retaliation by terminating a contract or giving differential treatment to a producer. A poultry industry trade association and several live poultry dealers said the retaliation provisions create a presumption that all grower protected activities are legitimate, which could open the door to strategically planned actions by poor performing growers designed to trigger these protections and would lead to especially severe risks if a grower has committed animal welfare violations.

AMS Response: AMS rejects the assertion that the rule would permit or encourage gaming by producers to avoid accountability for poor performance or violations of animal welfare guidelines. This final rule clearly specifies that the adverse action must be taken *based on* the producer participating in such protected activities. The mere coincidence, or correlation, between a producer joining an association or reporting to the government and then experiencing an adverse action is not enough for a violation. There must be evidence showing the adverse action taken by a regulated entity was in response to the producer engaging in a protected activity for a violation to be exist.

Additionally, AMS rejects the comment that the regulated entity would face a burden because it would not know which protected activities the producer has engaged in. The purpose of the rule is for the regulated entity to not adversely treat producers based on their participation in protected activities.

Comment: A poultry industry trade association and several live poultry dealers said the proposed rule also does not provide clarity regarding cooperative activity: live poultry dealers would still need to select which specific growers to contract with, choose where to place birds, and evaluate and approve housing and other grow-out specifications even if growers form cooperatives, but the proposed rule does not provide guidance on whether a regulated entity making these decisions might be considered to be engaging in retaliation.

AMS Response: A cooperative is a well understood legal status under the Co-Operative Marketing Associations (Capper-Volstead) Act of 1922 (Pub. L. 67–146) and protected by the Agricultural Fair Practice Act of 1967, which the proposed and final rule have both referenced. Generally, a cooperative is an organization established by individuals to provide themselves with goods and services or to produce and dispose of the products of their labor. The property of a cooperative, including the means of production and distribution, are typically owned in common. The final rule covers activities inherent in the planning and organization of a cooperative.

AMS also rejects the comment that live poultry dealers would still need to determine how to treat particular growers when dealing with a cooperative. Cooperatives are independent entities, and the live poultry dealer would enter in a contract with the cooperative as a whole, rather than with any individual grower. The terms of the general contract would govern the relationship between the live poultry dealer and the cooperative. Generally, a cooperative is an organization established by individuals to provide themselves with goods and services or to produce and dispose of the products of their labor. The property of a cooperative, including the means of production and distribution, are typically owned in common. This rule prohibits live poultry dealers from discrimination against a cooperative because it is a cooperative or from retaliating against producers for forming a cooperative. Because a cooperative is an entity, a regulated entity cannot assert that they are dealing with a cooperative but then limit the agreement to individuals.

Comment: A poultry industry trade association and several live poultry dealers urged AMS to introduce exceptions to the proposed rule's protection of information sharing activities under § 201.304(b)(2)(iv) and (v) that would cover confidential or proprietary information, saying that the

unauthorized release of confidential business information can harm businesses substantially and irreparably and therefore companies act legitimately in exercising their contractual rights to protect this information.

AMS Response: This rule will not create exceptions to existing laws governing the sharing of information between members of associations and cooperatives. Information sharing by associations remains governed by the Federal antitrust laws and other relevant laws. Certain conduct by cooperatives is exempt from the Federal antitrust laws. This rule does not change whether these activities are lawful and protected, or prohibited, under Federal law. AMS makes no changes in response to this comment.

xii. Other Comments on Retaliation

Comment: A whistleblower advocacy organization suggested several changes to expand the proposed rule's coverage. First, it recommended AMS extend the proposed rule's anti-retaliation protection to all natural or legal persons who provide information they reasonably believe is evidence of a violation of the Act or who refuse to take action they reasonably believe would violate the Act. According to the commenter, protected persons should include, but not be limited to, employees of meatpackers and integrators reporting violations of the Act; employees, contractors, and subcontractors of protected farmers or ranchers; and associates and relatives of protected persons or entities. Second, the commenter said that AMS should clarify language in the proposed rule stating that it does not protect farmers and ranchers acting in contravention of the Act from retaliation. According to the commenter, the final rule should exclude from protection only individuals acting without express or implied direction from the covered entity or its agent, and who deliberately and willfully cause a violation of any requirement relating to any violation or alleged violation under the Act. The commenter said this clarification would ensure that live poultry dealers cannot use this provision to attack farmers under broiler production contracts who engage in whistleblowing. According to this commenter, these contractors are subject to extreme corporate control that denies them the right to act under their own agency, so it would not be fair to exclude them from the protections against retaliation based on actions they could not control.

This commenter also said that, because farmers are often unfamiliar with protections that apply to their exposure of industry wrongdoing, USDA must make efforts to share information about producer rights and company responsibilities at the beginning of the contractual relationship as well as throughout the engagement. The commenter suggested that AMS host educational programming about rights under the Act and develop language-appropriate educational material. The commenter urged USDA and DOJ to continue to offer anonymous protected disclosures through their joint portal and be transparent about subsequent regulatory and enforcement activity, saying most producers prefer to make reports anonymously or through another party to avoid retaliation.

AMS Response: In this rule, AMS is principally focused on providing robust protections for covered producers participating in the market. Accordingly, AMS has not amended the regulatory text to extend the rule's coverage to all natural or legal persons who provide information regarding perceived violations of the Act or who refuse to take action they believe would violate the Act. AMS has, however, revised the regulatory text of § 201.304(b)(2)(i) to extend the coverage from a covered producer's communication ''with a government agency'' to communication ''with a government entity or official'' and from ''petitions for redress of grievances before a court, legislature, or government agency'' to ''petitioning a government entity or official for redress of grievances.'' AMS believes that this change ensures that protected communications may occur with any of the three branches of the Federal government and with individual government officials, including committees or members of a legislature. The regulation applies equally to communications with all levels of government—Federal, State, and local—with respect to the matters indicated.

Furthermore, AMS is sympathetic to and broadly in agreement with the commenter's perspective that covered producers should not be required to understand the precise contours of the Act to exert their protected activity rights, and that they should be enjoyed heightened protection when acting at the express or implied direction of a regulated entity. Regulated entities have no motive to purposefully induce producers to commit unlawful acts. If a regulated entity induces criminal activity, irrespective of retaliation, this inducement may be deceptive within the meaning of the Act.

AMS appreciates the commenter's advocacy regarding the need for continuing USDA-sponsored education regarding producer rights and company responsibilities under the Act. AMS is taking steps to increase producer education and outreach, including, for example, establishing the *farmerfairness.gov* portal to facilitate ease of access for submitting complaints. AMS intends to expand education and outreach regarding this rule and other regulatory requirements.

F. Recordkeeping (§ 201.304(c))

AMS proposed a recordkeeping requirement that records related to compliance with this rule be kept for a period of five years from the date of record creation. These records include policies and procedures, staff training materials, materials informing covered producers about reporting mechanisms and protections, compliance testing, board of directors' oversight materials, and records about the nature of complaints received relevant to prejudice and retaliation. AMS stated the purpose of this proposal was to reduce the threat of retaliation and to enhance AMS's ability to investigate and secure enforcement against undue prejudice and unjust discrimination.

i. Appropriateness of Proposed Regulation's Recordkeeping Obligations To Permit AMS To Monitor Regulated Entities for Compliance

AMS requested comment on whether the proposed recordkeeping obligations were appropriate to allow AMS to monitor regulated entities for compliance.

Comment: A group of State attorneys general and several organizations generally supported the proposed recordkeeping obligations in order to enhance compliance by regulated entities and enhance AMS's ability to monitor them for discriminatory treatment.

Other commenters supported the proposed recordkeeping requirements, but suggested AMS should require regulated entities to maintain additional specific records. A cattle industry trade association said AMS should require retention of any records that include specific terms (including prices paid) of purchase agreements or contracts, as well as any methodologies used to calculate premiums or discounts paid to producers. This commenter argued that such records would enable AMS to evaluate differential treatment. An agricultural advocacy organization made a similar suggestion for regulated entities to maintain income/payment formulas and pre-contract discussions with producers as part of their recordkeeping obligations.

AMS Response: AMS takes note of the commenters' support for the usefulness of the provisions. With respect to the request that AMS revise the rule to identify specific records that regulated entities must retain, AMS notes that the regulation as proposed provides flexibility for a regulated entity to retain any records relevant to its compliance with § 201.304(c), including records not specifically referenced in the regulation. Under sec. 401 of the Act, regulated entities are already required to maintain the accounts, records, and memoranda necessary to fully and correctly disclose all transactions involved in their business. USDA's implementing regulations can be found at 9 CFR 201.94, 201.95, and 203.4. Existing regulations under part 201 require regulated entities to give the Secretary ''any information concerning the business . . .'' (§ 201.94) and provide authorized representatives of the Secretary access to their place of business to examine records pertaining to the business (§ 201.95). Section 203.4 regulates the types of records that must be kept by regulated entities and the timelines for disposal of these records. As part of its enforcement capabilities under sec. 401 of the Act, AMS can inspect the records of regulated entities to review detailed information related to purchases and ensure that regulated entities are in compliance. Because these records are already required under existing law, AMS made no further changes in response to the comments.

Comment: A poultry industry trade association argued that the proposed recordkeeping regulation—as written—is not appropriate because it is vague and does not make clear that it only requires integrators to maintain records relevant to proposed § 201.304(a) and (b). The trade association contended that the rule should make explicit that, if a regulated entity does not maintain records relevant to those respective proposals, no recordkeeping is required. The commenter also recommended exempting privileged communications or attorney work product from the recordkeeping requirement.

AMS Response: AMS disagrees with the commenter's view that the regulation as proposed does not make clear that regulated entities are only required to maintain records relevant to proposed § 201.304(a) and (b): the regulation as proposed specifically stated that a regulated entity ''shall retain all records relevant to its compliance with paragraphs (a) and (b) of this section.'' Further, AMS does not believe it necessary to specify that certain records do not need to be retained if they are irrelevant because the regulatory text states explicitly that the recordkeeping requirement applies only to records relevant to a regulated entity's compliance with this section. Under the Act and existing PSD regulations, regulated entities are required to keep records pertaining to their business. To comply with the proposed regulation, a regulated entity must retain all records relevant to its compliance with § 201.304(a) and (b) for no less than five years from the date of record creation. Lastly, AMS does not believe that adding an exemption for privileged communication, such as attorney work product, is necessary because attorney work product is already protected from disclosure under current law. Therefore, AMS makes no changes to the rule in response to this comment.

ii. Requirements for Regulated Entities To Produce and Maintain Specific Policies, Compliance Practices, or Disclosures To Help Ensure Compliance With Undue Prejudice and Anti-Retaliation Provisions

AMS requested comment on whether the proposal should require regulated entities to produce and maintain their specific policies and procedures, compliance practices or certifications, or disclosures to ensure compliance with the undue prejudices and provisions and anti-retaliation provisions in the proposed rule.

Comment: Several commenters expressed concern that the proposed recordkeeping requirement would not be sufficient to ensure compliance. One organization argued that AMS should require regulated entities to proactively identify and record the basis of differential treatment (*e.g.,* differences in prices paid) among producers. An academic or research institution concurred, suggesting that any differential treatment in price or contract terms should be justified by regulated entities in their records.

An agricultural and environmental organization proposed regulated entities should be subject to an Annual Compliance Report to AMS that requires a detailed list of all their transactions. This list would include, specifically: (1) an anonymized list of producers the regulated entity did business with; (2) terms offered to producer during contract negotiations; (3) terms entered with producer and whether these terms differ with similarly situated producers; (4) prices paid to producers and methodology for the price; (5) whether AMAs were used; and 6) accounts of all instances of the regulated entity's refusal to deal with a producer and justification for the refusal. The commenter argued that it will be difficult for producers or AMS to prove violations of proposed § 201.304(a) without these detailed disclosures.

An agricultural advocacy organization proposed requiring regulated entities to report to AMS the contract terms and payments made to producers, as well as producer demographic information necessary to determine which producers are market vulnerable individuals. The commenter argued this was necessary to put the burden of enforcement of the new rule on AMS and regulated entities rather than covered producers. This commenter also suggested requiring regulated entities to use a uniform recordkeeping system that tracks and reports ''relevant data'' to allow AMS to monitor for potential differential treatment or discrimination. This commenter likened the proposed system to the Home Mortgage Disclosure Act, which allows regulators to use data from regulated entities to ensure compliance with fair housing laws.

AMS Response: AMS is making no changes to the rule as proposed based on this comment. AMS believes that the regulation as proposed permits flexibility for regulated entities to determine which records best demonstrate compliance with § 201.304. Such an approach is appropriate, given that this rule regulates the poultry, cattle, and swine industries, and that regulated entities vary in size and in the nature of their business operations. Regulated entities may have an existing recordkeeping system in place that is suited to their industry, size, or business operation. The proposed regulation's flexibility regarding the types of records that must be kept will ensure that the array of regulated entities covered by this rule can choose the method of compliance most relevant to their circumstances; the proposed regulation's specification that a regulated entity must retain all records relevant to their compliance with § 201.304(a) and (b) will aid in PSD's enforcement of paragraphs (a) and (b). As noted above, under sec. 401 of the Act, AMS is authorized to conduct compliance inspections, which may include examination of information related to differences in purchases and prices. AMS also has the power under sec. 6 of the FTC Act to require reports from corporations on a case-by-case basis. The additional reporting requirements suggested by commenters are outside the scope of this rulemaking, but AMS reserves the right to consider those approaches in future rulemakings.

Comment: A poultry industry trade association and several live poultry dealers said AMS should identify

specific records that need to be kept or generated, arguing that without specific guidance regulated entities will be left guessing which records are relevant to its compliance obligations.

AMS Response: As noted in the response above, this rule regulates a wide array of entities. Regulated entities may have an existing recordkeeping system in place that is suited to their industry, size, or business operation. Also as noted above, existing regulations and the Act require regulated entities to keep records of their business operations, subject to AMS compliance investigations. The regulation as proposed provides the flexibility for regulated entities to keep the types of records they deem appropriate to demonstrate their compliance with § 201.304, rather than requiring all regulated entities to keep the same set of records that may not be relevant to how they run their businesses. Paragraph (c)(2) provides a non-exhaustive list of examples of the types of records that may be relevant for a regulated entity to demonstrate compliance with § 201.304(a) and (b). AMS is making no changes to the rule as proposed based on this comment.

iii. Specific Challenges or Burdens Regulated Entities Might Face in Complying With Recordkeeping Duties of Proposed Rule

AMS sought comment on what specific challenges regulated entities may face in complying with the recordkeeping duties of the proposed rule.

Comment: A poultry industry trade association and several live poultry dealers said that the proposed recordkeeping rule was overly broad, such that regulated entities would need to document and maintain every document related to interactions with producers (such as emails, visits, or notes from calls or meetings). The commenters raised concerns that this obligation would impose an overwhelming administrative burden and exorbitant compliance costs on regulated entities, which would be compounded by the 5-year record maintenance requirement. They suggested reducing the requirement period to two years. An agricultural association shared these concerns, in particular around the possibility that communications with any person about potentially entering into a contract may be deemed relevant under the rule and that, as such communications could be directed at any employee, a regulated entity could have to maintain records of all communications with its employees for a period of five years. This commenter said, if USDA interprets the recordkeeping requirements in this broad manner, would impose a particular burden on smaller entities subject to the recordkeeping requirement since these entities lack the administrative or IT infrastructure necessary to comply. A legal foundation also posited that the recordkeeping proposal would impose significant costs on regulated entities and—to reduce their burden—urged AMS to impose a warrant requirement before requiring disclosure of records.

AMS Response: AMS is making no changes to the regulation as proposed. The recordkeeping requirement in this rule is not new. PSD currently has recordkeeping authority through the Act and its existing regulations, including sec. 401 of the Act, and 9 CFR 201.94, 201.95, and 203.4. Further, AMS subject matter experts—economists and supervisors with years of experience in AMS's PSD conducting inspections and compliance reviews—have estimated the recordkeeping costs associated with this rule to be relatively low. They have estimated that recordkeeping costs would be correlated with the size of the regulated entity, with the assumption that the hour burden would be highest for the largest entities. Therefore, at the highest end of the spectrum, AMS has estimated that annual recordkeeping compliance costs for the largest regulated entities would average of 4 hours of administrative assistant time and 1.5 hours of time each for managers, attorneys, and information technology staff in the first year. Thereafter, for the largest entities, annual recordkeeping compliance costs would average 3 hours per year of administrative assistant time, 1.5 hours per year of manager and attorney time, and 1.00 hour of time from information technology staff. As stated previously, AMS estimates that the hour burden would decrease proportionate to the size of the entity. AMS also notes that some firms might not have any records to store, while other firms may already store relevant records and may have no new costs associated with this rule. It also notes that the list of suggested records in § 201.304(c)(2) is illustrative and that regulated entities are not required to document and maintain all of these records. Therefore, AMS estimates that the compliance costs associated with this rule will be relatively low and, as these costs are likely to vary in proportion to the size of the regulated entity, smaller entities are unlikely to face particular burdens. The objective of the recordkeeping requirement is to support USDA monitoring efforts as well as to preserve the flexibility of allowing regulated entities to decide how best to comply with the rule. It is incumbent upon regulated entities to decide which records are relevant for rule compliance.

AMS is also declining to revise the regulation to limit the record retention requirement to two years. AMS believes that requiring that records be retained for five years from their creation date will enable the agency to monitor the evolution of compliance practices over time in this area and will ensure that records are available for what may be complex evidentiary cases. AMS will not be adding a warrant requirement to the rule at this time because the Agency already has jurisdiction under the Act to request documents concerning a regulated entity's business and therefore no warrant is required to do so under governing law.[194]

iv. Ways in Which Recordkeeping Duties Differ From Existing Policies, Procedures, and Practices of Regulated Entities

AMS requested comment on how the proposed recordkeeping duties may differ from the current policies, procedures, or practices of regulated entities.

Comment: A poultry industry trade association and several live poultry dealers argued that the proposal to include board of directors and other corporate governance materials as a matter of routine compliance with the Act is not typical of compliance records maintenance. The commenters suggested that these materials would not be helpful in demonstrating violations of the proposed rule, and their inclusion may be an attempt to create liability for executives or board members for everyday regulatory requirements.

AMS Response: AMS is making no changes to the rule as proposed based on this comment. The rule does not require regulated entities to maintain board of directors' materials. These materials are referenced in the rule as an example of the types of records that may be relevant for a regulated entity to demonstrate that it has complied with § 201.304(a) and (b). Therefore, regulated entities are not required to retain these materials. However, AMS notes that the conduct of executives and board members is a critical component in establishing a corporate culture of

[194] Section 201.94 of the regulations requires regulated entities to give the Secretary ''any information concerning the business . . .'' Section 201.95 of the regulations requires that regulated entities provide authorized representatives of the Secretary access to their plaice of business to examine records pertaining to the business.

compliance. As noted previously, a culture of compliance is a critical tool for preventing legal and regulatory violations and a first step toward more inclusive market practices.

G. Deceptive Practices (§ 201.306)

AMS proposed to prohibit regulated entities from participating in several types of deceptive practices with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry. These relate to contract formation, performance, termination, and refusal.

i. Accuracy and Adequacy of Proposed Regulations in Identifying Recurrent Deceptive Practices in Livestock and Poultry Industries

AMS requested comment on whether the proposed regulations accurately and adequately identify recurrent deceptive practices in the livestock and poultry industries, as well as whether any areas of deception may be missing.

Comment: Commenters including a group of State attorneys general, several organizations, and an academic institution indicated support for the deceptive practices provisions, with one commenter saying the provisions would clarify the duties of regulated entities to engage in honesty and market integrity.

Two agricultural advocacy organizations recommended that, in addition to the four broad prohibitions on behavior enumerated under proposed § 201.306, AMS should provide a non-exhaustive list of prohibited conduct known to harm producers, saying this measure would provide clear guardrails and foster quicker termination of abusive practices against producers. These commenters also said the deception provisions of the proposed rule fall well within AMS's authority under the Act, noting that Congress gave USDA broad powers under the Act with the intention of halting unfair trade practices against producers before producers suffer actual harm.

AMS Response: AMS is making no changes to the rule as proposed. AMS appreciates the views expressed by commenters but believes specifying the duties of regulated entities to engage honestly and itemizing prohibited deceptive practices adds unnecessary complexity. Firstly, specific guidance as to what constitutes deceptive practices can be taken from existing regulations in 9 CFR part 201, such as: §§ 201.49 and 201.71 (requiring honesty in weighing); § 201.53 (requiring honesty in representation of market conditions or prices); § 201.98 (requiring honesty in collection of fees); § 201.67 (prohibiting deception regarding the nature of packer and selling agency business relationships); and § 201.217 (requiring transparency regarding breach of contract determinations). Secondly, in the event deception occurs in ways actionable under sec. 202(a) of the Act, yet that violation is not specifically covered by this rule, AMS will look to the legislative history and case law of the Act to guide its handling of these matters. For example, obvious falsehoods, such as false weighing and false accounting have always been considered deceptive practices under sec. 202(a) of the Act. Therefore, AMS believes it is not necessary to itemize such practices in this particular section. Lastly, AMS underscores that this rule is intended to provide a broad array of coverage regarding the general circumstances that encourage the provision of false or misleading information. Facts and circumstances are unique to every case and may vary significantly; therefore, AMS has determined to retain the four broad prohibitions on behavior under § 201.306 as initially proposed.

Comment: A poultry industry trade association said all actions prohibited under proposed § 201.306 are already addressed in sec. 202(a) of the Act, which prohibits regulated entities from engaging in unfair, unjustly discriminatory, or deceptive practices or devices.

AMS Response: AMS is making no changes to the rule as proposed based on this comment. AMS agrees that the prohibitions established by this rule are well within the scope of sec. 202(a) of the Act. This rule is designed to help producers better understand what behavior constitutes a violation of sec. 202(a). Based on complaints and comments from stakeholders over the years, as well as in response to the proposed rule, AMS is aware that deceptive practices continue to harm producers and market integrity. Thus, AMS has determined it necessary to codify in its regulations deceptive practices prohibited under sec. 202(a) of the Act to better ensure that producers benefit from the protections intended by the passage of the Act.

ii. Specific Deceptive Practices

AMS proposed prohibiting regulated entities from:

- Making or modifying a contract by employing a pretext, a false or misleading statement, or an omission of a material fact necessary to make a statement not false or misleading (§ 201.306(b)).
- Performing under or enforcing a contract by employing a pretext, false or misleading statement, or omission of material fact necessary to make a statement not false or misleading (§ 201.306(c)).
- Terminating a contract or taking any other adverse action against a covered producer by employing a pretext, false or misleading statement, or omission of material fact necessary to make a statement not false or misleading (§ 201.306(d)).
- Providing false or misleading information to a covered producer or association of covered producers concerning a refusal to contract (§ 201.306(e)).

Comment: An agricultural advocacy organization suggested the final rule's explanatory text should clarify that deceptive practices related to contract formation also include the making of false or misleading statements to prospective producers on the benefits of a contractual relationship with a regulated entity. The commenter said that this clarification would, for example, better address circumstances such as representatives of live poultry dealers who make verbal claims to prospective growers about benefits not reflected in the actual contract the grower later receives to sign.

AMS Response: AMS is not making the specific changes to proposed § 201.306(b) requested in this comment but is making changes to this paragraph to clarify the range of deceptive conduct prohibited during contract formation. AMS agrees with the commenter regarding the harm of false statements in contract formation. AMS formulated § 201.306(b) specifically to address the making of false statements in contract formation. The revised regulation states that not only is a regulated entity prohibited from employing a ''false or misleading statement'' but it also may not omit ''material information necessary to make a statement not false or misleading.'' Therefore, AMS believes the regulation encompasses the protection against misleading statements requested by the commenter. AMS will address the specific circumstances raised by the commenter via other rulemakings.

Comment: An agricultural advocacy organization pointed out a potential discrepancy, saying the range of deceptive behavior in contract formation, performance, and termination covered in § 201.306(b) through (d) of the proposed rule as drafted appears narrower than that contemplated in the proposed rule's preamble. The commenter noted that the preamble said USDA generally approaches deceptive practices from the perspective of a reasonable party

receiving them and asks whether they would affect the conduct or decision of a reasonable recipient of these practices and asserts that the Act reaches beyond common-law fraud to affirmatively require honest dealing and truthfulness in the marketplace.[195] The commenter said that, if AMS intended the description in the preamble to encompass a broader range of deceptive behavior than that in the proposed rule's current language, it should broaden the language in § 201.306(b) through (d) of the proposed rule to prohibit any practices likely to mislead a covered producer, acting reasonably under the circumstances, to the producer's detriment.

AMS Response: There is not a contradiction or discrepancy between the preamble and the proposed regulation. The preamble discusses deception more generally, providing background on AMS's approach to implementing the prohibition on deceptive practices and its legal authority to do so under sec. 202(a) of the Act. The regulatory text is designed to provide example prohibited deceptions under the Act. It is not designed to enumerate every circumstance that may be a prohibited deceptive practice under the Act. There are circumstances where a deceptive practice could be covered under sec. 202(a)'s prohibition on deceptive practices even if that practice is not expressly addressed by this final rule. AMS chose not to provide an exhaustive coverage of every possible circumstance that could be a deceptive practice because such an effort would be unwieldly as a matter of rulemaking and likely offer little benefit to producers in terms of making the protections of the Act concrete and understandable. Such an effort would require such breadth of coverage and flexibility in application as to effectively replicate the interpretive process that is needed to analyze deceptive practices under the Act, which may vary significantly depending on the facts and circumstances of each case. In this rule, AMS has instead chosen to strike a balance, and is offering clear protection for a broad range of commonly encountered circumstances. AMS notes that the regulatory text in paragraphs (b) through (d) does include a prohibition on employing a ''false or misleading statement.'' Therefore, AMS is making no changes to the regulation as proposed.

Comment: Agricultural advocacy organizations urged AMS to expand and clarify the proposed rule's prohibition on deceptive conduct during contract refusal, saying regulated entities can use this tactic to manipulate producers, as they may do with contract termination. The commenters gave the example of a dominant buyer who only wants to purchase cattle from producers locked into AMAs, rather than those selling on a negotiated cash market, so it can pay lower than fair market value. If this buyer simply tells producers on the open cash market that it does not need their cattle, this statement may not necessarily be false or misleading, but it would be a pretextual justification for refusing to deal with them. A cattle industry trade association also urged AMS to ban the practice of refusing to buy a producer's cattle in the negotiated cash market unless the producer agrees to enter a forward contract, saying this practice is so widespread that it is common knowledge among cattle producers that packers who say they do not need their cattle are tacitly providing them with an ultimatum.

Several commenters recommended the following amended regulatory text, with changes in bold:

''(e) Contract refusal. A regulated entity may not **rely on a pretext or** provide false or misleading information to a covered producer or association of covered producers concerning a refusal to contract.''

AMS Response: AMS has designed the prohibition on deceptive practices in refusal to contract differently than the prohibition for other circumstances because the relationship between a regulated entity and a covered producer differs in this circumstance. During contract formation, performance, or termination, there is a high degree of reliance by the covered producer on the regulated entity, owing to the existence of the contract. In a refusal-to-contract circumstance, however, the reliance is limited principally to the denial of the opportunity to transact. In general, regulated entities may refuse to contract with a covered producer for any reason or no reason at all, unless the reason is impermissible under the Act. This final rule's prohibition on deception seeks to ensure that any reasons provided by the regulated entity to the producer are truthful and not misleading. Failure to provide such truthfulness is deceptive because, given the high levels of vertical integration and horizonal concentration, producers lack marketing options and thus heavily depend on regulated entities for market integrity and, ultimately, the information needed to compete effectively. Producers are harmed when they cannot evaluate their competitive opportunities in an honest, objective manner. While the USDA Extension Service and other third parties may assist producers in appreciating their competitive strengths and weaknesses, ultimately the signals sent by packers are critical for competitive opportunities.

The final rule does not include ''pretext'' or ''omission of material fact necessary to make a statement not false or misleading'' in this refusal to contract provision because refusals to contract may occur for any number of reasons, and regulated entities may not always be in a position to reveal the reason for a refusal to contract. There may be economic, social, community, or even simply polite reasons for offering an incomplete, if not untruthful, reason for a refusal to contract. As long as a regulated entity is not providing false or misleading information to a covered producer or omitting material information, it will not run afoul of § 201.306(e).

AMS appreciates the commenter's concerns regarding the use of forward contracts. However, including a specific prohibition regarding this practice was not under consideration in the proposal. With this rulemaking, AMS is implementing regulations to provide a broad array of coverage against deceptive practices during various stages of the contracting process. Deceptive acts in contract refusal will be determined on a case-by-case basis based on the facts and circumstances of each individual case. In the example raised by the commenter, were a packer to refuse to purchase cattle in the cash market and state that its plant has acquired all the cattle it needs, the packer would not run afoul of the final rule if that statement was true. However, were the packer to make such a statement but would be willing—or attempt—to purchase the cattle under a different marketing arrangement, that would suggest that the information provided was false or misleading and the packer would run afoul of the final rule. If the cattle were of a quality or type that the packer does not want and the packer has already acquired all the cattle it needs for a given week, the packer could state that it is full without telling the covered producer its real reason for refusing to purchase cattle—again, as long as the statement provided is truthful.

Accordingly, AMS is not making any changes to the regulation as proposed in response to these comments.

iii. Recurrent Deceptive Practices Not Adequately Addressed by Proposed Regulations

AMS asked whether there were recurrent deceptive practices not

[195] 87 FR 60010, 60032, 60034, October 3, 2022.

adequately addressed by the proposed regulations.

Comment: Several organizations recommended AMS add the clause ''but is not limited to'' to § 201.306(a) to provide flexibility regarding other deceptive actions that may arise.

AMS Response: AMS is not adopting the recommendation. ''Not limited to'' language is unnecessary, as paragraphs (b) through (e) of this section are not stated as being exhaustive. This regulation is not designed to, and should not be read to, create an exclusive or exhaustive set of instances of deceptive practices. This rulemaking is intended to provide guidance to covered producers for how to effectuate their rights under the Act by implementing regulations that provide a broad array of coverage against deceptive practices during various stages of the contracting process. Future rulemaking or enforcement actions would not be restricted to the conduct identified in § 201.306 when dealing with deception, as the Act's coverage is broader than this final rule.

Comment: An agricultural advocacy organization recommended that AMS address common cattle contracting practices that enable regulated entities to consolidate their power, expand their profit margins, and shift their risks to producers, particularly those practices facilitated by increased use of AMAs. The commenter asserted AMAs, which are typically contracts for future delivery of cattle where the price paid at time of delivery is tied to a contemporaneous price such as that in the ''spot'' cash market for cattle, give packers ample opportunity to offload the risks of changes in the spot market onto producers by manipulating the prices they pay them at delivery. The commenter cited several ways in which the prevalence of AMAs shapes the market to packers' advantage. According to the commenter, animals under AMAs contribute, along with those directly owned by packers, to a large ''captive supply'' of cattle for packers, which gives these regulated entities substantial control over the cash price of beef. In addition, the commenter said lack of participation in spot markets means they provide less reliable price signals for AMAs, allowing packers to easily conduct limited spot market sales at low prices, in turn lowering the prices they pay producers at time of delivery.

The commenter argued that many of these packer practices relating to AMAs are deceptive because they can induce producers to enter into contracts in which they do not fully appreciate the extent to which packers control the applicable risks. At a minimum, the commenter urged AMS to clarify that the proposed rule's ban on deceptive practices extends to packer manipulation of spot market prices to lower the price paid to independent producers at time of delivery. The commenter also stressed that it would prefer AMS to introduce a comprehensive prohibition of deceptive practices associated with AMAs to avoid placing the burden of identifying manipulation on individual producers. Specifically, the commenter recommended that AMS require forward livestock contracts to include a firm and predictable base price, so packers have no room to manipulate prices, citing the recent Cargill case under which DOJ alleged that contracts executed by major poultry processor defendants under the tournament system violated the Act. The final judgment agreed to by the parties and entered by the Court requires that the defendant processors pay contract poultry growers a firm and predictable base price.[196] The commenter also suggested AMS consider banning packer-owned cattle as well as captive supply arrangements that use formula or basis price forward contracts.

AMS Response: AMS is aware that concerns exist around forward cattle contracts and AMAs, especially those linked to thin cash markets. AMS is not addressing in this rulemaking whether AMAs are inherently deceptive. Therefore, AMS will not include a blanket prohibition on such contracting in this rule.

Likewise, AMS has determined it will not add the commenter's suggested ban on packer-owned cattle and captive supply arrangements that use formula or basis price forward contracts. AMS believes more analysis is needed to ensure such intervention is appropriate.

Comment: An agricultural advocacy organization recommended that AMS add a provision to § 201.306 establishing a standard for contract completeness and providing that use of contracts that do not meet these minimum standards constitutes an unlawful deceptive practice under the Act. The commenter argued this measure would help producers operating in monopolistic regional markets, saying integrators often take advantage of the lack of buyer-side competition by unilaterally dictating base prices, providing deceptive earnings claims, offering incomplete and one-sided contracts leaving out key terms such as the number of flocks a poultry grower can expect to receive, and coercing producers into taking on additional debt to upgrade their facilities. The commenter recommended that the proposed rule specify that complete contracts include the expectation that contracts clearly state a minimum price or rate of pay for products or services rendered; a detailed disclosure of potential expected capital investments necessary for a continued contractual relationship; and a minimum commitment of contract years, annual animal placements, and stocking density sufficient for the producer to maintain any contractually expected debt payments at the minimum guaranteed price or payment rate. The commenter also suggested AMS clarify that it would be unlawful retaliation for an integrator to coerce, intimidate, or break contract with a producer based on the producer's unwillingness to implement integrator-desired upgrades not previously detailed in a complete contract, as long as the producer's infrastructure is legally compliant and in good working order.

AMS Response: AMS understands that in highly concentrated buyer markets, producers may have limited control over contract terms due to the limited availability of buyers; however, AMS will not be establishing minimum standards for contract completeness via this rulemaking. This rule is intended to address broad areas of specific concern, not exhaustively identify all deceptive practices that could violate sec. 202(a) of the Act. Deceptive acts in contracting will be determined on a case-by-case basis based on the facts and circumstances of each individual case. Similarly, AMS will not be amending the regulations prohibiting retaliation (§ 201.304(b)) to implement the commenter's specific circumstance regarding unwillingness to implement upgrades not previously detailed in a complete contract. This comment is outside the scope of this rulemaking and AMS is making no changes to the rule based on this comment.

Comment: Agricultural advocacy organizations asked AMS to include a new paragraph enumerating a non-exhaustive list of prohibited conduct, saying this addition would clarify that the Act explicitly prohibits certain conduct known to harm producers and market integrity. The commenters further said AMS should include any other specific types of harmful conduct producers currently face and stress that all other conduct known to harm producers or market integrity is prohibited even if not directly listed. The commenters provided the following

[196] *See* U.S. v Cargill Meat Solutions Corp., et al. at *https://www.justice.gov/d9/2023-11/418169.pdf.*

recommended regulatory text to incorporate these suggested changes:

(f) *Specific deceptive practices prohibited*.[197] In addition to any other conduct prohibited by subsections (b) through (e), a regulated entity may not engage in the following conduct during contract formation, performance, or termination or when refusing to contract:

(1) Demanding capital investments as a condition of contract renewal if such capital investment demands were not previously agreed to in writing between the covered producer and regulated entity.

(2) Demanding capital investments by a covered producer without commensurate and enforceable obligations on the part of the regulated entity that will reasonably allow the covered producer to recover the demanded capital costs plus a reasonable return.

(3) Refusing to deal because the livestock producer is selling livestock on the cash market rather than through a contract arrangement and the livestock is otherwise marketable.

(4) Failing to provide a guaranteed base pay in Alternative Marketing Agreements, production contracts, or other similar arrangements.

(5) Inequitably distributing inputs such as animal placements, feed, veterinary care, or other inputs controlled by a regulated entity that can impact a covered producers' performance or compensation.

(6) Shifting environmental compliance costs or responsibilities exclusively to a covered producer when the regulated entity exercises substantial operational control, through contract or otherwise, over the producer through an ownership interest in the livestock or poultry, land or other capital, or control of a covered producers' activities, inputs, management and waste management practices, or capital investments.

AMS Response: AMS is making no changes to the rule based on this comment. The commenters' proposed specific prohibitions are outside the scope of the deceptive practices AMS intended to address in this rule.

Comment: Agricultural advocacy organizations suggested AMS look to the poultry transparency proposed rule [198] and the advance notice of proposed rulemaking regarding fairness and related concerns in poultry grower tournament systems,[199] saying AMS should ensure that the deceptive practices identified in these rulemakings, such as unfounded claims about potential earnings made to prospective contract growers, lack of transparency in explaining tournament results, and inconsistent input quality, are also incorporated into this rule.

AMS Response: AMS is making no changes to the rule based on this comment. This final rule seeks to provide a broad set of protections for all producers. Other rules that AMS may propose or finalize, including rules relating to poultry grower ranking systems, are separate and distinct.

iv. Approach to Governance and Structuring of Deception and Employing False or Misleading Statements

AMS requested comment on whether deception in contract refusal should be governed by the categorial approach as proposed, or whether it should be governed by a single statement setting out one standard for contract formation, performance, and termination. It also requested comment on whether it should structure deception around prohibiting the deceptive pretext, statement, or omission, rather than prohibiting the contractual activity based on the deceptive statement or omission as proposed. In addition, it requested comment on whether the prohibitions on ''employing'' certain false or misleading statements, pretexts, and omissions in the formation, operation, etc., of a contract appropriately capture the importance or effect of the misleading statement, such as its material or relevance to the producer or the formation, operation, etc., of the contract. Alternatively, it asked whether it should prohibit a regulated entity from employing any pretext, false or misleading statement, or omission of material facts necessary to make a statement not false or misleading, in connection with making, enforcing, or cancelling a contract. AMS also asked if there was a better way to approach the issue, such as using elements or defenses.

Comment: An agricultural advocacy organization said the categorical approach to governance in the rule as proposed is appropriate because itemizing the likely deceptive actions more effectively draws attention to the various deceptive actions potentially used by regulated entities. This commenter indicated that either approach to structuring would be effective but said the structure as proposed would better make current producers and prospective aware of the types of potential deception they may encounter. It also indicated support for the approach to employing of false or misleading statements, pretexts, or omissions AMS took in the proposed rule.

AMS Response: AMS takes note of the commenter's support for the usefulness of the provisions. AMS made no changes to the rule in response to this comment; however, as discussed in Section V—Changes from the Proposed Rule, AMS made several changes to the verbiage of § 201.306(b) through (d), including removing the word ''pretext'' and replacing the phrase ''omission of material fact'' with ''omission of material information.''

v. Other Elements To Explicitly Consider in Rule on Deception

AMS requested comment on whether there are other elements, such as the reasonableness of the recipient, that it should explicitly consider in a rule on deception.

Comment: An agricultural advocacy organization said AMS should consider whether the contract language was clear and written in a language the producer understands when evaluating if a regulated entity used deceptive practices. The commenter also said the proposed rule on transparency in tournament systems addressed disclosure-related issues that AMS should consider in establishing when contract terms should be considered deceptive.

AMS Response: Whether the contract language was clear and written in a language the producer understands would be part of any evaluation to determine whether a statement (including any omission of material information) was false or misleading and that determination would be dependent on the particular facts and circumstances of the contract. This rule is intended to cover not only the poultry industry, but the swine and cattle industries. As such, it focuses on general circumstances that may give rise to the provision of false or misleading information. Therefore, AMS is making no changes to the rule based on this comment.

vi. Specific Challenges or Burdens Regulated Entities Might Face in Complying With Deceptive Practices Provisions of Proposed Rule

AMS requested comment on specific challenges or burdens regulated entities might face in complying with the deceptive practices provisions of the

[197] The commenters noted that, if AMS adopts this addition, it must also revise § 201.306(a) to include paragraph (f): ''A regulated entity may not engage in the specific deceptive practices prohibited in paragraphs (b) through (f) of this section.''

[198] Agricultural Marketing Service, ''Transparency in Poultry Grower Contracting and Tournaments,'' Proposed Rule (87 FR 34980, June 8, 2022), available at *https://www.federalregister.gov/documents/2022/06/08/2022-11997/transparency-in-poultry-grower-contracting-and-tournaments.*

[199] Agricultural Marketing Service, ''Poultry Growing Tournament Systems: Fairness and Related Concerns,'' Request for Comments (87 FR 34814, June 8, 2022), available at *https://www.federalregister.gov/documents/2022/06/08/2022-11998/poultry-growing-tournament-systems-fairness-and-related-concerns.*

proposed rule and how they differ from existing policies, procedures, and practices of regulated entities.

Comment: A poultry industry trade association and several live poultry dealers said the deceptive practices provisions of the proposed rule would discourage legitimate adverse actions by companies, making the system less efficient overall. First, the commenters said AMS does not provide guidance on how it defines ''pretext'' or how a regulated entity would demonstrate that an explanation is not pretextual, which raises uncertainties in terms of compliance and may dissuade companies from providing detailed explanations to producers to avoid the potential for second-guessing on motive. The commenters also said the proposed rule is unclear about whether regulated entities seeking to avoid a potential omission of material fact need to mention every business reason that contributed to a decision even if other factors were more relevant. In addition, the commenters said the proposed deception provision makes it more challenging to terminate relationships with contractors who perform poorly or mistreat animals, giving regulated entities incentive to keep these contracts in place rather than risk lawsuits over whether any communications leading up to the termination were deceptive and resulted in fewer opportunities for new entrants to the poultry industry.

A swine industry trade association said the deceptive practices provisions would likely lead to costly litigation because the rule is overly broad and vague in its description of prohibited conduct. For example, according to the commenter, the proposed rule does not provide any definition or guidance on what constitutes a ''material'' fact, which is deceptive if omitted, and its ban on deceptive practices with respect to ''any matter'' related to livestock, meats, or live poultry does not clearly establish the scope of conduct at issue. In addition, the commenter said much of § 201.306 is unnecessary because other laws already sufficiently restrict the conduct at issue.

AMS Response: Section 201.306 is designed to address deceptive practices in the marketplace by establishing four categories in the contracting process where deceptive practices commonly occur. The aim is to promote a marketplace that is free from the type of injury the Act was designed to prevent. Such a framework is necessarily broad, as the commenters noted, however, this framework is not intended to, and should not, cripple regulated entities' decision-making or the system overall.

AMS must help ensure that regulated entities are truthful in their dealings with producers. Under these rules, AMS would seek to uncover the real motive for a regulated entity's treatment of a producer with whom they are forming or have a contractual relationship. AMS is including a prohibition against false or misleading statements, or omission of material information necessary to make a statement not false or misleading (in paragraphs (b) through (d)) to protect producers from conduct that employs deceit to disguise a regulated entity's genuine motive. Over the years, producers have reported concerns regarding their inability to understand and appreciate the real reasons why regulated entities take certain actions against them, in particular with respect to certain actions such as reduced chick placement or contract termination. For example, producers have asserted that sometimes a regulated entity will suddenly enforce certain parts of a contract in a stricter manner—such as animal welfare guidelines—even though the regulated entity had earlier found the producer's conduct under the contract acceptable. Producers assert that this is an example of a form of retaliation for actions by the producer or a deceptive practice to accommodate unrelated economic decision-making. Producers need to understand the real reasons for regulated entities' decision-making both to protect themselves from specific inappropriate adverse actions (such as undue prejudice or retaliation) and to be able to compete more effectively in a concentrated marketplace. If they cannot learn the real reasons why certain actions are taken against them, they cannot plan or mitigate the risks they may face. Therefore, AMS believes it is crucial to establish a regulatory framework prohibiting deceptive practices in contracting. AMS believes such a framework should provide broad, non-exhaustive prohibitions to provide better coverage for producers against deceptive practices in various stages of the contracting process. AMS may refine this framework via future rulemakings if the need arises.

With respect to the commenters' view that AMS does not provide guidance on how it defines ''pretext'' or how a regulated entity would demonstrate that an explanation is not pretextual, AMS adopted clarifying language by withdrawing its use of ''pretext'' and relying on the prohibition against employing a ''false or misleading statement.''

With respect to the commenters' critiques regarding the materiality standard, under the FTC's Policy Statement on Deception, ''material'' refers to information that would affect a consumer's—in this case, producer's—conduct or decision-making, from the perspective of a producer acting reasonably under the circumstances. Act precedent may not require AMS to follow FTC's precedent in all circumstances, but AMS has designed the rule to satisfy the approach set forth in the FTC Policy Statement on Deception in this set of deceptive practice prohibitions. AMS is not seeking to establish a ''but for'' standard; however, the materiality of the information is already embedded in the regulated entity's act of ''employing'' the omission on which the covered producer has relied on in the contracting activity under § 201.306. Commenters also expressed concern about § 201.306's prohibition against the omission of material facts, questioning whether compliance would require that regulated entities mention every business reason that contributed to a decision even if other factors were more relevant. AMS notes that proposed § 201.306(b) through (d) specified that the prohibition applies to the ''omission of material fact necessary to make a statement not false or misleading.'' If one of the factors that contributed to a regulated entity's business decision was not material or relevant, then the omission of that information would be unlikely to make a statement false or misleading from the perspective of a producer acting reasonably under the circumstances. AMS therefore made no changes to the proposed regulations in response to this comment; however, AMS notes that as discussed in Section V—Changes from the Proposed Rule, AMS made several changes to the verbiage of § 201.306(b) through (d), including replacing the phrase ''omission of material fact'' with ''omission of material information.''

In response to commenters' concerns regarding the potential for increased litigation, AMS acknowledges that the provisions of § 201.306 could result in additional litigation because the regulations could provide producers new hope for relief from deceptive conduct in the contracting process. However, as discussed in more detail in this rule's Regulatory Impact Analysis in Section VIII.B., AMS does not expect large increases or decreases in litigation from this rule. Though commenters expressed concern that this regulation will lead to costly litigation because it is too broad and vague, AMS notes that in this final rule the Agency has provided additional clarity on the meaning of ''material'' in these

regulations and removed use of the word pretext. AMS also rejects the commenter's assertion that the rule is overly broad and vague in its ban on deceptive practices with respect to ''any matter'' related to livestock, meats, or live poultry because this assertion is inaccurate. This regulation does not ban any deceptive practice related livestock, meats, or live poultry: paragraph (a) establishes that the scope of § 201.306 is prohibiting deceptive practices that occur in specific stages of the contracting process. These stages are then delineated in paragraphs (b) through (e). AMS notes, however, that it has removed the words ''any matter'' from § 201.306(a).

With respect to the commenter's view that § 201.306 is unnecessary, AMS disagrees. AMS believes that, while USDA regulations prohibiting specific deceptive practices already exist, a regulatory framework prohibiting deception during the contracting process is necessary because this will provide much-needed certainty and predictability to the interpretation of this section of the Act.

vii. Specific Recordkeeping Provisions Relating to Deceptive Practices

AMS requested comment on whether it should propose specific recordkeeping provisions relating to deceptive practices and what such practices should include.

Comment: An agricultural advocacy organization recommended that AMS introduce a recordkeeping requirement related to deceptive practices to help it enforce these practices. Another agricultural advocacy organization suggested AMS require regulated entities to provide examples of contract terms as well as procedures related to tournament settlements and input quality, saying this requirement would help it identify deceptive practices.

AMS Response: In response to commenters' suggestions, AMS notes that regulated entities are already required to maintain records pertaining to their business activities (see 9 CFR 201.95). In light of existing law, a specific recordkeeping requirement covering every statement or interaction that could amount to deception is not appropriate as it could be expensive and burdensome, while yielding little benefit in terms of usable, searchable information. AMS will monitor regulated entities' practices to evaluate whether additional requirements are necessary. AMS further notes that should specific problems emerge, heightened recordkeeping could be a requirement arising out of enforcement actions or adopted in future rulemaking.

AMS is not adopting the commenter's suggestion regarding examples of contract terms and procedures related to tournament settlements and input quality because they are outside the scope of this rule. AMS made no further changes in response to the comments.

viii. Requirement That All Contracts be in Writing

AMS requested comment on whether all contracts with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry should be in writing.

Comment: Agricultural advocacy organizations said AMS should require all contracts to be in writing because doing so is necessary for enforcing the Act. These commenters said AMS should also require regulated entities to make all claims to prospective producers in writing to deter false or misleading statements designed to encourage signing of a contract.

A plant worker indicated support for requiring all contracts to be in writing, while noting that some benefits would be limited. According to the commenter, introducing this type of requirement would help producers by providing a record of the transaction and an increase in transparency. However, the commenter also said such a requirement would be less likely to address packer pressure on producers to use formula market arrangements to incentivize cattle quality if the packers present these arrangements as take-it-or-leave-it offers, although it would at least help create an environment that is transparent about material terms. The commenter also said that many jurisdictions may already require contracts to be in writing to satisfy the statute of frauds, especially if they cover multiple years, thus making a provision requiring written contracts potentially redundant in some cases.

AMS Response: AMS appreciates the commenters' views on the value of written contracts and agrees that written contracts have significant benefits for reducing deceptive practices and encouraging market integrity. Written contracts provide both parties clearer understanding of their positions and the opportunity for regulators to review and evaluate the functioning of the market. However, AMS also recognizes that it is a longstanding trade practice in the agricultural sector for many parties to negotiate and assent to contract terms orally, which holds the same weight under the law as a written contract. USDA has pursued many cases based on the violation of unwritten terms, and this will not change. Requiring that all contracts be in writing would more significantly affect cattle markets, as more of those markets remain cash-negotiated. Contract formation regarding the purchase and sale of livestock often occurs over the phone and quickly. Requiring written contracts would impede the ability of parties to conduct business expeditiously, which is often necessary in fluctuating commodity markets, especially for perishable products like meat. Vertically integrated contract growing arrangements, which are nearly universal in poultry and widespread in hogs, are more characterized by written contracts already. In this rule, AMS is choosing not to adopt a requirement for written contracts or claims in all circumstances. While AMS believes that written contracts are a good practice, especially in light of changes in technology (like email and electronic signatures), AMS believes additional study and consideration is needed and is deferring for future consideration whether a mandate is appropriate.

ix. Treatment of Failure To Continue To Buy in Cash Market Following Regular Pattern or Practice of Such Buying

AMS requested comment on whether a failure to continue to buy in the cash market, following a regular or dependable pattern or practice of such buying, should be treated for the purposes of this proposed rule as more similar to termination of a contract, rather than as refusal to deal.

Comment: An agricultural advocacy organization said it agreed with AMS that a decision or action on the part of a regulated entity to stop buying on the cash market is more analogous to a contract termination than a refusal to deal but notes that these decisions or actions also share key features with the latter. The commenter provided the example of a packer who refuses to buy cattle in the cash market from a covered producer who regularly sells on the cash market unless the producer agrees to enter a forward contract with a packer; this act would constitute both refusal to deal and termination of a contract, and would also be a form of prohibited retaliation.

AMS Response: AMS agrees that a circumstance where a packer refuses to buy cattle in the cash market from a covered producer who regularly sells on the cash market to the regulated entity is analogous to a contract termination, as past court decisions have recognized a remedial duty under the Act to a make purchases in certain circumstances.[200]

[200] *Swift & Co.* v. *United States,* 393 F.2d 247, 253 (7th Cir. 1968).

AMS did not make any revisions to § 201.306 in response to this comment; however, AMS is clarifying in § 201.304(b)(3)(iv) of this final rule that refusing to deal with a covered producer refers to refusing to deal on terms generally or ordinarily offered to similarly situated covered producers, which would include the producer's prior status quo. This would address the case where a producer has a prior track record of regular sales to the packer but is cut off. AMS also added § 201.304(b)(3)(vi) to further clarify that harm to a producer on the basis of protected activities is intended broadly to capture materially adverse retaliatory action that a packer may take against a producer.

H. Severability (§ 201.390)

AMS proposed adding a new provision to 9 CFR part 201 of the Packers and Stockyards regulations ensuring that if any provision—or applicability of any provision—of subpart O was declared invalid, the validity of the other provisions of subpart O would be unaffected. AMS noted this is to provide a reviewing court some guidance on the Agency's position on how the rule is intended to function.

Comment: An agricultural advocacy organization indicated support for the severability provision, saying that, in the event of successful court challenges to specific provisions of the proposed rule, it would help ensure that the protections in the rest of the rule remain.

AMS Response: AMS agrees that a severability clause is appropriate because the undue prejudice, retaliation, and deception sections of this rule can be enforced as stand-alone provisions. They are not interdependent, therefore the exclusion of one does not disqualify any of the others. For this reason, as discussed in more detail in Section VI.F—Provisions of the Final Rule, Severability, AMS has included under § 201.390 a severability clause in its final rule.

I. Effective and Compliance Dates

Comment: An industry company said AMS should consider what amount of time is necessary to implement changes resulting from its new rules, and recommended it provide one effective date for all regulatory changes required by updates to the Act.

AMS Response: AMS agrees with commenters that the final rule should provide a clear effective date for implementation. The AMS Act final rule ''Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyards Act'' was published on December 11, 2020, and became effective on January 11, 2021, providing a 30-day period. AMS believes that this rule presents a similar scope of rulemaking coverage, relating to basic principles that regulated entities themselves have acknowledged they already comply with. However, in response to requests from commenters for additional time, AMS will give 60 days, which the Agency feels provides adequate time for regulated entities to become compliant with this rule given the low cost and minimal process changes required to do so. Accordingly, within 60 days of publication in the **Federal Register**, regulated entities are expected to comply with all components of new subpart O.

J. Regulatory Notices & Analysis & Executive Order Determinations

i. Costs and Benefits of Proposed Rule

Pursuant to the requirements of Executive Order 12866, AMS conducted a cost-benefit analysis of the proposed rulemaking by considering three regulatory alternatives: (1) maintaining the *status quo* and not implementing the proposed rulemaking, (2) issuing the proposed rulemaking, or (3) issuing the proposed rulemaking but exempting small businesses from compliance with the recordkeeping requirement.

a. Costs of Proposed Rule

Comment: Several live poultry dealers and trade associations took issue with the accuracy of cost estimates in the proposed rulemaking. A poultry industry trade association and several live poultry dealers contended that the Agency's first-year estimate of $504 per live poultry dealer to comply with the proposed rule is a drastic underestimate. They argued that the costs of physical filing cabinets to maintain the requisite paperwork alone would exceed the estimated first-year cost, and that recordkeeping and computer systems to digitally maintain records would be more costly. The commenters also contended that the AMS cost estimates overlooked significant labor costs that would be required to comply with the new rules, including legal services.

AMS Response: AMS disagrees with commenters' assertions regarding the accuracy of its cost estimates. AMS subject matter experts calculated the estimated compliance and recordkeeping costs associated with this rule. These experts are economists and supervisors in AMS's PSD with many years of experience conducting investigations and compliance reviews. AMS stands behind their estimates. AMS believes that the costs associated with this rule will be minimal: the first-year total cost is estimated to be $586,000, or 0.0002 percent of revenues, given that total sales of beef, pork, and broiler chicken was approximately $294.5 billion in 2022.[201] This figure encompasses an estimate of the total value of the time required to review and learn the rule, review live poultry dealers' and packers' procurement policies and production contracts, make any necessary changes to ensure compliance with the new regulations, and maintain records to demonstrate compliance practices. AMS estimates that the total cost for each succeeding year would be $298,000, or 0.0001 percent of revenues.

With respect to commenters' assertion that AMS has neglected to account for labor costs, including legal services, AMS notes that in the proposed rule's Paperwork Reduction Act analysis, AMS provided a compliance cost breakdown for the hours required of attorneys, as well as administrative assistants, managers, and information technology staff. AMS does not expect large increases or decreases in litigation costs, and thus regulated entity legal services. The clarity provided by the rule encourages regulated entities to proactively avoid prejudicial, discriminatory, and deceptive practices that could otherwise lead to costly litigation. Likewise, the rule could also provide producers hope for relief from the courts for perceived prejudicial, discriminatory, and deceptive practices, which could, in turn, increase litigation but would return benefits to producers in reduced harms. In response to commenters' concerns regarding the costliness of the rule's recordkeeping requirements, AMS argues that the recordkeeping requirements were crafted to provide flexibility for regulated entities. The rule does not prescribe the manner in which records must be stored. If a regulated entity finds the cost of filing cabinets prohibitive, the entity may choose whichever means of file retention is most cost effective, including currently available computer filing systems, which most companies maintain in the normal course of business. Additionally, the rule provides regulated entities leeway to determine which records they choose to maintain. Because this rule applies to regulated entities across a

[201] Total meat and poultry processing industry revenues. Source: *https://www.ibisworld.com/industry-statistics/market-size/meat-beef-poultry-processing-united-states/#:~:text=The%20market%20size%2C%20measured%20by,industry%20increased%200.2%25%20in%202022.*

variety of industries and of varying sizes, AMS did not prescribe a set of records each entity must retain, regardless of their relevance to a particular entity's circumstances. Some firms might not have any records to store. Others may already store relevant records and may have no new costs. Therefore, the rule saves regulated entities from the burden of maintaining records irrelevant to their circumstances.

Accordingly, AMS makes no changes to the rule in response to these comments.

Comment: Many industry companies and trade associations argued that the cost estimates put forward in the proposed rule ignore significant litigation costs that would be inevitable under the proposed regulations. A cattle industry trade association disagreed with AMS's cost analysis that the rule could plausibly reduce litigation costs ''if companies come into compliance without any enforcement action.'' The trade association argued that the rule contains vague standards and eliminates the requirement that a plaintiff must show competitive harm, both of which would lead to a proliferation of litigation. It asserted that the threat of litigation would cause packers to reduce their legal risk exposure by standardizing their contracts with producers, which could be costly for producers who benefit from contracts tailored to their individual needs or conditions (*e.g.,* cattle weight targets based on geographic location and regional feedstuffs availability). Finally, it noted that AMS itself acknowledged that GIPSA declined finalizing the agency's proposed rule in 2016—the Farmer Fair Practices Rule—because it contained ambiguous terms that would increase litigation between regulated entities and producers.

A live poultry dealer echoed this concern, citing USDA's acknowledgement in the previously proposed 2016 Farmer Fair Practice Rule that rolling back the harm to competition requirement would ''inevitably lead to more litigation in the livestock and poultry industries.'' [202] The dealer also said that if the proposed rule is implemented, the company would no longer have incentive to contract with individuals due to litigation risk and would need to rely more heavily on company-owned farms to raise its poultry. It argued that the result would be decreased grower competition and thus decreased grower pay, resulting in another unmeasured cost of the proposed rule.

An industry trade association suggested that millions of dollars per year would be required to litigate, define, and refine the terms of the new rule due to ambiguity. It said that frivolous litigation that misunderstands or capitalizes on vagueness in the rule would add significant litigation costs. The trade association estimated the cost of compliance with the new rule (including anticipated litigation) to be more than $100 million to the industry. It cited independent economic analyses of previous AMS rulemakings on similar topics that estimated economic impact costs exceeding $1 billion,[203] arguing that AMS significantly underestimates cost estimates in the new proposed rule.

AMS Response: Litigation is possible following the passage of any rule. The threat of such litigation does not preclude AMS from fulfilling its mandate to administer the Act. AMS believes that discriminatory, retaliatory, and deceptive practices only serve to exclude qualified producers from the market. Even if such conduct impacts a single producer, it can reasonably be inferred that, if unchecked, such conduct will proliferate and negatively impact other producers and the market. Therefore, it is the opinion of the Agency that such conduct must be stopped in its incipiency, or it will likely cause widespread harm.

In response to commenters' complaint that AMS has overlooked significant litigation costs that would be inevitable under the proposed regulations, AMS does not expect large increases or decreases in litigation costs. The clarity provided by the rule encourages regulated entities to proactively avoid prejudicial, discriminatory, and deceptive practices that could otherwise lead to costly litigation. This effect would lead to a decrease in litigation costs. Likewise, the rule could also provide producers hope for relief from the courts for perceived prejudicial, discriminatory, and deceptive practices, which could, in turn, increase litigation costs but would return benefits to producers in reduced harms. AMS is uncertain as to which effect will dominate and to what extent and, therefore, does not estimate litigation costs in this analysis.

With respect to the comments regarding compliance costs for the 2016 Farmer Fair Practice Rule, commentors discussed that a trade association estimated the cost of compliance with rule (including anticipated litigation) to be more than $100 million to the industry. A commentor also noted that an independent economic analyses of previous AMS rulemakings on similar topics that estimated economic impact costs exceeding $1 billion. The 2016 Farmer Fair Practice Rule was a very different proposed rule with a much wider scope than this final rule, and AMS does not consider a comparison of the 2016 Farmer Fair Practice Rule and this final rule to be an accurate comparison. The costs of this final rule are much smaller than the estimated costs of the 2016 Farmer Fair Practice Rule. GIPSA estimates the average litigation cost of the 2016 Farmer Fair Practice Rule to be less than $9 million in the first year. Given the scope of this final rule is smaller than the 2016 Farmer Fair Practice Rule, AMS expects litigation to be smaller. This, combined with the offsetting effects of the increases and decreases in litigation, leads AMS to not consider adding litigation costs to the rule.

The assertion that packers will be forced to standardize all contracts to ensure conformity with the rule is without basis. Standardizing contracts may be one way to ensure fair treatment of producers, however, this rule in no way mandates such a response from packers. Similarly, AMS disagrees with the assertion that fear of litigation would remove any incentive to contract with individual poultry growers. The aim of the rule is to discourage abuses of power in the marketplace to allow qualified producers to participate freely in the market and receive full value for their efforts. Reliance on individuals to raise poultry evolved as an economically advantageous way for integrators to bring poultry to the market. AMS does not believe that a greater focus on ensuring honest dealing and honest decision-making is incompatible with this model. Further, AMS disagrees with the assumption that a regulated entity would need to abstain from contracting with individuals to ensure that they are not abusing their market power by operating in prejudicial, retaliatory, or deceptive ways.

With respect to the comments regarding rules previously published by GIPSA, AMS notes that GIPSA's withdrawal of its 2016 rules was justified in part due to the rules' lack of clarity regarding prohibited behavior and the agency's perception that such ambiguity would increase litigation costs. This rule differs from the GIPSA rules by more clearly and specifically laying out the types of conduct that will

[202] *Org. for Competitive Mkts.* v. *Dep't of Agriculture,* 912 F.3d 455, 459 (8th Cir. 2018) (quoting 82 FR 48594, 48597 (Oct. 18, 2018)).

[203] Scope of §§ 202(a) and (b) of the Packers and Stockyards Act, 81 FR 92566, 92576, December 20, 2016 (discussing cost estimates prepared by Thomas Elam and Informa Economics).

be prohibited. Additionally, much has changed since the withdrawal of GIPSA's 2016 rules. In 2017, GIPSA merged with AMS. AMS now administers regulations under the Act and undertook this rulemaking to meet its statutory mandate. Also, in the years since the GIPSA rules were withdrawn, USDA has continued to receive complaints from producers regarding undue prejudice and unfair, unjustly discriminatory, and deceptive practices. When Congress, in April 2022, held hearings to discuss such concerns regarding the cattle and poultry markets, the hearings were marked by the absence of producers who chose to avoid public testimony for fear of retribution.[204] Meanwhile, the market remains highly concentrated and vertically integrated, which enables market power abuses and unjust distortions of the competitive landscape and makes any harms from them more significant. Smaller producers are unable to freely compete and receive fair value for their goods because in highly concentrated markets they often have no option but to do business with regulated entities which, in AMS's experience, have caused producers to experience unjust and adverse treatment. AMS has not been able to effectively address these complaints, partly because of the lack of clarity regarding its regulations under the Act and the ability for individuals to bring cases based on specific instances of harm. Therefore, it is now the Agency's belief that the potential costs of increased litigation are outweighed by the benefits to the market as a whole.

With respect to the ''vague standards'' giving rise to increased litigation specifically, AMS has taken note and addressed clarity in this rule.

Further, AMS will review the facts and circumstances of each case and the regulated entity's justifications for any alleged adverse treatment to determine whether the regulated entity has violated this rule. AMS is making no changes to the rule in response to these comments.

Comment: A plant worker argued that—given the modest cost estimates AMS provided for regulated entities to administratively comply with the recordkeeping requirements ($231–$485 for first-year costs and less in succeeding years) of proposed § 201.304(c)—consideration of the third regulatory alternative put forth by AMS was unnecessary. The commenter reasoned that because over 95 percent of packers reporting to AMS are small businesses, exempting such a large part of the industry would not be conducive to creating a uniform standard of recordkeeping and reducing deceptive practices across the industry.

AMS Response: AMS agrees with the commenter that the third regulatory alternative was not the best option. AMS opted to proceed under regulatory alternative two, the proposed alternative. AMS chose to publish its legal and economic analysis regarding the third alternative to provide better transparency to the public regarding the Agency's decision-making process. AMS is making no changes to the rule in response to this comment.

AMS chose final §§ 201.304 and 201.306 over the Small Business Exemption Alternative because AMS wishes to prevent the kind of undue prejudices and unjust discrimination described in the rule. AMS believes that keeping relevant records will help promote compliance with this rule, that all packers, live poultry dealers, and swine contractors cannot purchase livestock or enter into contracts for growing services with the kind of undue prejudices and unjust discrimination described in the rule. All packers, live poultry dealers, and swine contractors cannot purchase livestock or enter into contracts for growing services with the kind of undue prejudices and unjust discrimination described in the rule.

b. Other Comments on the Cost-Benefit Analysis

Comment: An agricultural advocacy organization contended that AMS should clarify the role of litigation costs in its cost-benefit analysis. It argued that litigation resulting from proposed rulemaking should not be treated purely as a cost, since (1) changes in behavior by regulated entities to reduce violations of the Act and (2) compensatory awards to market participants that suffer from violations of the Act both result in benefits that AMS should weigh in calculating the net costs of the proposed regulation. The association said that the Act relies in part on private litigation to keep livestock markets competitive, and while AMS is right to be cognizant of litigation costs by providing clear and unambiguous language to forestall unnecessary legal proceedings, litigation in general should not be treated solely as an ancillary cost without considering the benefits it confers.

AMS Response: AMS is making no changes to the rule in response to this comment. Rulemaking procedure regarding the calculation of costs and benefits requires the inclusion of specific costs. The benefits of litigation are harder to quantify, and thus were not specifically included in the proposed rule. However, AMS agrees with commenter that there are benefits of litigation in that producers will be better able to protect themselves from undue prejudice, retaliation, and deception, and thus that litigation does not result solely in negative costs. By adding private rights of action to the Act as recently as 1987, Congress has expressly recognized that private litigation, or the threat thereof, is a force that shapes conduct for the protection of producers. To the extent that the threat of private litigation pressures regulated entities into compliance and keeps their conduct fair, litigation risks can serve to ensure this rule's full potential is realized.

K. Comments on Legal Authority or Other Legal Issues

i. Statutory Authority Under the Act

Comment: Several live poultry dealers, an industry company, industry associations, a legal foundation, and an individual argued the proposed rule exceeds AMS's authority because it unlawfully seeks to transform the Act from an antitrust statute into a civil rights law despite Congress's clear intention to address the type of harm to producers covered by the proposed rule via other statutory schemes rather than under the auspices of the Act. They argued that, if these laws still do not cover certain types of mistreatment producers may face, the correct course of action is for Congress to revise these statutes or pass new ones, not for AMS to attempt to address them via the Act. For example, a cattle industry trade association noted that 42 U.S.C. 1981 already prohibits racial discrimination in private contracting in cases where the contractor cannot show harm to competition. The cattle industry trade association contended that, because Congress has never sought to expand the protections of section 1981 to other protected categories, AMS lacks authority to use the Act to effectively do

[204] *See* House Chair David Scott D–GA, Opening remarks, U.S. House, Committee on Agriculture, ''An Examination of Price Discrepancies, Transparency, and Alleged Unfair Practices in Cattle Markets,'' April 27, 2022, (14 min: 24 sec), available at *https://anchor.fm/houseagdems/episodes/An-Examination-of-Price-Discrepancies--Transparency--and-Alleged-Unfair-Practices-in-Cattle-Markets-e1hpvo8/a-a7r40dk. See also* U.S. Senate Committee on Agriculture, Nutrition, and Forestry, ''Legislative hearing to review S. 4030, the Cattle Price Discovery and Transparency Act of 2022, and S. 3870, the Meat and Poultry Special Investigator Act of 2022,'' April 26, 2022, (1 hour 39 min), available at *https://www.agriculture.senate.gov/hearings/legislative-hearing-to-review-s-4030-the-cattle-price-discovery-and-transparency-act-of-2022-and-s3870-the-meat-and-poultry-special-investigator-act-of-2022* (Described fear of retaliation in livestock and poultry markets).

so in the absence of enabling legislation. This commenter also noted that multiple other USDA statutes explicitly refer to socially disadvantaged groups and socially disadvantaged farmers or ranchers, saying the lack of such references in the Act itself indicates that Congress did not intend for issues relating to exclusion or disadvantage of covered producers to fall within its scope. A swine industry trade association said proposed § 201.304(a) of the proposed rule covers conduct already prohibited by the Act itself as well as by other antitrust and anti-discrimination laws, such as the Civil Rights Act of 1964, the Agricultural Fair Practices act, and the Robinson-Patman Act. Industry trade associations and companies said other statutes such as the Agricultural Fair Practices Act, the Capper-Volstead Act, and laws protecting farmers from retaliation if they act as witnesses in a Federal investigation already prohibit retaliation against essentially all covered activities under proposed § 201.304(b).

AMS Response: Consistent with the Act, this rule protects inclusive competition and market integrity, and is designed to ensure that fair and competitive conditions prevail in livestock and poultry markets. While this rule may in some ways resemble certain civil rights laws, it is distinct as it draws its authority from the Act, which sets forth a general prohibition on unjust discrimination and undue prejudice that is broader than civil rights statutes that focus solely on discrimination on account of a protected status. AMS believes that discrimination on the basis of an individual's characteristics—in particular, the bases (as set forth in § 201.304(a)) of race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, or marital status, or age, and the producer's status as a cooperative)—has no place in the market for livestock and poultry. Prejudices, disadvantages, inhibitions on market access, or otherwise adverse actions against covered producers on these bases must fundamentally be viewed as unjust forms of discrimination, lest the word *unjust* be unmoored from its plain meaning. Moreover, this rule addresses the unique and often difficult-to-prove discriminatory conduct that has long existed in the agricultural sector. Demographic information is seldom recorded in agricultural transactions; therefore, it is difficult to quantify discrimination. However, as the preamble set forth, agricultural markets are not representative of the population as a whole, for reasons in part arising from a well-established track record of unjust discrimination from USDA itself. Unjust discrimination on the bases set forth in this rule does not stem solely from USDA's actions, rather it was widespread across society. Discrimination and prejudice have not been eliminated from society, and heightened steps are appropriate to prevent unjust discrimination from coloring public or private decision-making. Such clarity is especially important in today's highly concentrated agricultural markets, with few minority participants, as the lack of competition means that failure of inclusion for all farmers gives rise to a competitive harm under the Act.

AMS recognizes that section 1981 of the Civil Rights Act establishes that certain rights are to be guaranteed, and these rights are to be protected against impairment by nongovernment and state discrimination. This rule addresses prohibited conduct specifically in the agricultural sector and is not superseded by section 1981. By expressly stating prohibited conduct that is violative of the Act, this rule seeks to allow AMS to better enforce the Act. AMS acknowledges that multiple USDA-administered statutes explicitly refer to socially disadvantaged groups and socially disadvantaged farmers or ranchers but underscores that AMS has replaced the definition of ''market vulnerable individual'' (which was more closely aligned with the formulations under those laws) with a simpler set of prohibited bases. And for the reasons described above, AMS's interpretation of the Act is faithful to its text and purposes. AMS notes that comments indicated that the Act in fact does prohibit the conduct set forth in this rule, in which case the rule will function to clarify and explicate already prohibited conduct.

AMS notes commenters' argument that § 201.304(a) covers similar conduct as the Civil Rights Act of 1964, the Agricultural Fair Practices Act (AFPA), and the Robinson-Patman Act. However, the fact that such conduct is prohibited under those statutes does not mean that it is not also prohibited by the P&S Act, which is broader in scope than other antitrust laws.[205] AMS believes it is appropriate to provide clarity regarding application of the Act because AMS has the authority to enforce the Act (and the AFPA), and not the Civil Rights Act of 1964 or the Robinson-Patman Act, with respect to livestock and poultry. The Act provides supplemental and parallel coverage to the AFPA, making its application appropriate and valuable to livestock producers and poultry growers who have, over the years, found it challenging to earn the full value of their animals in their dealings with packers and live poultry dealers.

Similarly, AMS disagrees with commenters' argument that § 201.304(b), which prohibits retaliation, is unnecessary because these protections are already afforded by the AFPA, the Capper-Volstead Act, and other laws which specifically protect farmers from retaliation for acting as a witness in a Federal investigation. USDA has continually received complaints from producers regarding retaliatory practices. Therefore, AMS concludes that promulgating these rules under the authority of the Act is necessary to address these concerns.

Therefore, AMS makes no changes to the rule as proposed in response to these comments.

Comment: A legal foundation and a cattle industry trade association claimed AMS's decision to broadly restrict discrimination against ''market vulnerable'' individuals exceeds its statutory authority. One commenter said this decision, and its likely result of leaving courts to flesh out the vague definition to determine whom the proposed rule should protect, is inconsistent with Congress's longstanding and repeated choices to ban discrimination using an approach based on protected classifications. Another commenter said AMS acts beyond its authority in proposing a broad definition of ''market vulnerable'' individuals because its goal in taking such an approach is to ensure that the rule can address prejudice based on categories such as sexual orientation or gender identity. According to the commenter, AMS cannot redefine the meaning of the key terms ''undue prejudice'' and ''unjust discrimination'' under the Act to include protections based on these categories because the Congress that enacted the Act in 1921 would not have contemplated such protections. The commenter further critiqued AMS's citation of *Bostock* v. *Clayton County*[206] to support its approach. According to the commenter, *Bostock,* which establishes that discriminating against an individual for being lesbian, gay, transgender, or

[205] H.R. Rep. 67–77, at 2 (1921); *see also Swift & Co.* v. *United States,* 308 F.2d 849, 853 (7th Cir. 1962) (''The legislative history showed Congress understood the sections of the [P&S Act] under consideration were broader in scope than antecedent legislation such as the Sherman Antitrust Act, sec. 2 of the Clayton Act, 15 U.S.C. 13, sec. 5 of the Federal Trade Commission Act, 15 U.S.C. 45 and sec. 3 of the Interstate Commerce Act, 49 U.S.C. 3.'').

[206] 140 S. Ct. 1731, 1741 (2020).

queer, constitutes discrimination on the basis of sex or gender prejudices, is in fact limited to an employment context and does not apply to contract arrangements.

AMS Response: AMS accepts the comment that it would be burdensome for the courts to flesh out the vague definition of ''market vulnerable individual'' to determine who the proposed rule should protect and that the approach is inconsistent with Congress's longstanding and repeated choices to ban unjust discrimination using an approach based on protected classifications. Accordingly, AMS is adopting specific prohibited bases in this final rule.

AMS rejects the commenter's view that it is beyond the authority of the Act for AMS to address prejudice based on categories, such as sexual orientation or gender identity, because the Congress that enacted the Act in 1921 would not have contemplated such protections. The Act specifically addressed ''unjust discrimination'' and ''undue prejudice'' and left it to the Secretary to set out the scope of equitable terms such as ''unjust'' and ''undue,'' as well as ''unfair.'' [207] Moreover, ECOA prohibitions on discrimination in the extension of credit—which includes many of the protected bases covered by this final rule, including sex, shall be enforced under the P&S Act. Therefore, a violation of ECOA (if committed by a regulated entity) is also violation of the P&S Act.[208] It is widely accepted, following *Bostock* v. *Clayton Cnty* [209] and other cases, that the term ''sex'' covers sexual orientation and gender identity and the categorization as such is not limited to employment law.[210] Moreover, since 2014, USDA has prohibited discrimination on those bases in all of USDA's Conducted Programs.[211]

Comment: Industry trade associations said proposed § 201.304(a) inappropriately fails to incorporate the requirement from section 202(b) of the Act that a prejudice or disadvantage be ''undue or unreasonable'' to constitute a violation. The commenters said this provision would go against precedent which has concluded that the Act, as well as the broader antitrust regime, allows actions such as refusal to deal or non-renewal of a contract when conducted reasonably. One commenter said AMS exceeds its authority in omitting this statutory requirement from the proposed rule.

AMS Response: Under Act precedent, the Secretary is authorized to determine whether discriminatory conduct is ''undue'' or ''unreasonable.'' [212] The Secretary has in the past interpreted similar provisions governing stockyards to include prohibitions on discrimination on similar bases.[213] Moreover, multiple precedents interpret the unfair practices provisions of sec. 5 of the FTC Act to incorporate discrimination on race, sex, and similar prohibited bases.[214] The ICA's provisions barring unjust discrimination too, have been interpreted to bar discrimination on the protected bases.[215] Therefore, this rule is within the Secretary's authority under secs. 202(a) and (b) of the Act. Under Act precedent, whether discriminatory conduct amounts to being ''undue'' or ''unreasonable'' is a determination that the statute provides broad discretion to the Secretary to determine. Advantages are not a component of this rule instead the rule focuses on prohibiting conduct that disadvantages producers based on characteristics unrelated to the quality of their products or services.

Comment: Multiple industry companies and associations, another organization, and an individual contended that AMS unlawfully rejected precedent by asserting that discriminatory conduct can violate secs. 202(a) or (b) of the Act without demonstrating injury, or likelihood of injury, to competition. The commenters cited legislative history and judicial precedent to argue that the Act is fundamentally an antitrust statute and is thus bound by the key antitrust principle of preventing harm to competition. Commenters said Congress's main concern in enacting the Act was preventing harm to competition from meatpacker monopolies and that, in drafting the Act, Congress used the basic blueprint of the Sherman Act and other existing antitrust statutes, which distinguish between fair competition and undesirable predatory competition. Commenters said interpreting secs. 202(a) and (b) to require plaintiffs to prove actual or likely harm to competition thus promotes the Act's main purpose of protecting healthy competition in the meatpacking industry. Commenters also cited numerous court cases holding that the Act requires a showing of injury to competition, including rulings spanning eight circuits.[216] The commenters argued AMS's approach would open the door to baseless litigation and increased costs to industry. A commenter argued that, in the absence of the harm-to-competition standard, courts will use a range of inconsistent means to establish violations of the Act, meaning individual cases will more likely require judicial resolution despite AMS's claim that its proposed approach will reduce litigation.

AMS Response: Congress designed the Act to provide broader protections than existing antitrust laws such as the Clayton and Sherman Acts due to specific challenges in agricultural markets.[217] The existence of the Act is proof that existing antitrust laws were not sufficient in protecting livestock producers and ensuring fair agricultural markets. It is well established that, to meet the needs of livestock producers more effectively, the Act provides broader protections than existing antitrust laws. The statutory text, case law, and legislative history make plain that the Act's protections extend beyond

[207] Section 407 of the Act (7 U.S.C. 228) provides that the Secretary ''may make such rules, regulations, and orders as may be necessary to carry out the provisions of this Act.''

[208] 15 U.S.C. 1691c(a)(5).

[209] 140 S. Ct. 1731, 1741 (2020).

[210] *https://www.consumerfinance.gov/about-us/newsroom/cfpb-clarifies-discrimination-by-lenders-on-basis-of-sexual-orientation-and-gender-identity-is-illegal/.*

[211] *https://www.federalregister.gov/documents/2014/07/16/2014-16325/nondiscrimination-in-programs-or-activities-conducted-by-the-united-states-department-of-agriculture.*

[212] *Mahon* v. *Stowers,* 416 U.S. 100, 112 (1974)). Section 407 of the Act (7 U.S.C. 228) also provides that the Secretary ''may make such rules, regulations, and orders as may be necessary to carry out the provisions of this Act.''

[213] Statement of General Policy Under the Packers and Stockyards Act published by the Secretary of Agriculture in 1968 (Statement of General Policy) (9 CFR 203.12(f)).

[214] *See Federal Trade Commission* v. *Passport Automotive Group, Inc., No. 8:22–cv–02670 (D. Md. filed Oct. 18, 2022)* (Settlement resulting from FTC allegations that Passport's discriminatory conduct, including charging Black and Latino customers interest-rate markups not tied to creditworthiness, violated the ''unfairness'' prong of Section 5 of the FTC Act); Michael Kades, ''Protecting Livestock Producers and Chicken Growers,'' *Washington Center for Equitable Growth* (May 5, 2022), available at Protecting livestock producers and chicken growers—Equitable Growth.

[215] *See* 7 U.S.C. 193. *Cf. Mitchell* v. *United States,* 313 U.S. 80, 94 (1941)).

[216] *Terry* v. *Tyson Farms, Inc.,* 604 F.3d 272, 276–79 (6th Cir. 2010); *Wheeler* v. *Pilgrim's Pride Corp.,* 591 F.3d 355 (5th Cir. 2009) (en banc); *Been* v. *O.K. Indus., Inc.,* 495 F.3d 1217, 1230 (10th Cir. 2007); *Pickett* v. *Tyson Fresh Meats, Inc.,* 420 F.3d 1272, 1280 (11th Cir. 2005), *cert. denied,* 547 U.S. 1040 (2006); *London* v. *Fieldale Farms Corp.,* 410 F.3d 1295, 1303 (11th Cir.), cert. denied, 546 U.S. 1034 (2005); *IBP, Inc.* v. *Glickman,* 187 F.3d 974, 977 (8th Cir. 1999); *Philson* v. *Goldsboro Milling Co.,* 1998 WL 709324 at *4–5 (4th Cir., Oct. 5, 1998); *Jackson* v. *Swift Eckrich, Inc.,* 53 F.3d 1452, 1458 (8th Cir. 1995); *Farrow* v. *United States Dep't of Agric.,* 760 F.2d 211, 215 (8th Cir. 1985); *De Jong,* 618 F.2d at 1336–37; *Pac. Trading Co.* v. *Wilson & Co.,* 547 F.2d 367, 369–70 (7th Cir. 1976); see also *Armour & Co.,* 402 F.2d 712.

[217] *See In re Pilgrim's Pride,* 728 F.3d 457, 460 (5th Cir. 2013) *Been,* 495 F.3d at 1231 *Swift & Co.* v. *US,* 393 F.3d 247, 253 (7th Cir. 1968) *Swift & Co.* v. *United States,* 308 F.3d 849, 853 (7th Cir. 1962).

antitrust laws.[218] Accordingly, it has been the Agency's longstanding position that because the Act addresses more and different types of harmful conduct than antitrust laws, a showing of competitive injury is not required to establish violations of secs. 202(a) and 202(b). Market abuses such as deception, unjust discrimination, and retaliation are illegal per se under the act. Addressing the harmful conduct this rule aims to prevent is squarely within the authority of the Secretary and accords with Congressional intent.[219] Moreover, the Secretary, exercising broad authority to define the scope of secs. 202(a) and (b), has determined that the prohibited practices are likely to exclude producers from the market, thereby lessening competition and causing widespread marketplace harm if not addressed in their incipiency, before competitive injury has occurred.

Commenters cite several circuit court decisions that required a showing of harm to competition or a likely harm to competition establish a violation of sec. 202. These cases involved private claims and do not control the Agency's statutory authority to promulgate regulations. AMS is within its statutory authority to promulgate rules that ''assure fair competition and fair-trade practices, to safeguard farmers and ranchers . . . to protect consumers . . . and to protect members of the livestock, meat, and poultry industries from unfair, deceptive, unjustly discriminatory and monopolistic practices. . . .'' Congress granted the Secretary broad authority to determine the scope of coverage of terms such as ''unjust discrimination'' and ''undue prejudice'' or ''unreasonable disadvantage'' under secs. 202(a) and (b) of the Act.

This rule aims to prevent market exclusion of producers who have been subjected to unjust discrimination on a prohibited basis or based on engaging in a protected activity, and to snuff out those harms at their incipiency. Based on its knowledge of the industry, AMS has determined that undue and unreasonable prejudice and unjust discrimination on the prohibited bases and the protected activities identified in the rule amount to conduct that negatively effects these markets, and therefore AMS is establishing these regulations to address that conduct at its incipiency, when it occurs against a single individual.

Additionally, deceptive conduct violative of the Act has routinely been enforced on an individual basis absent a required showing of any particularized harm to competition since the very first administrative actions brought by the Department. Deceptive conduct often takes the form of unfair contract formation, enforcement, and termination and therefore most frequently occurs on an individual basis. To require a showing of harm to competition to prove deception violations under the Act would be contrary to longstanding enforcement standards and is adverse to the intent of the Act to protect farmers and ranchers from deception. Furthermore, the assertion from commenters that this rule will result in costly ''baseless'' litigation is contrary to the findings of AMS. AMS has determined that this rule will not increase litigation significantly due to the assertion by regulated entities, through their comments, that they do not engage in the conduct this rule aims to prohibit.

Comment: Several advocacy organizations and a cattle industry trade association supported AMS's position that prohibited conduct under the Act need not lead to market-wide harm to competition, with some urging AMS to explicitly state that a showing of such harm is not required under the proposed rule. An agricultural and environmental organization cited E.O. 14036 on Promoting Competition in the American Economy,[220] which called for a rule explicitly stating individuals should be able to prevail under the Act without proving market-wide harm. This commenter argued AMS needs to explicitly state its position to stop judicial confusion in the face of a Federal circuit court split on the competitive-harm issue. The commenter said that, since the proposed rule contains multiple references to both USDA's position on market-wide harm to competition and E.O. 14036's explicit direction to incorporate this position into a final rule, amending the rule to clearly adopt this position would be a logical outgrowth of the proposed rule.

An agricultural advocacy organization contended the text, structure, and legislative history of the Act indicate that it prohibits discrimination based on market-vulnerable and protected-class status, giving AMS the legal authority to promulgate regulations based on this interpretation. The commenter argued the Act's prohibition of differential treatment on an ''unjust,'' ''undue,'' or ''unreasonable'' basis encompasses all forms of discrimination based on a producer's market vulnerability or protected classification because it includes all actions that adversely differentiate between producers without a legitimate basis. The commenter said that, in using such words in the Act, Congress clearly intended to invoke national values and policies related to fairness and equal treatment, including equal protection jurisprudence as it existed during enactment. According to the commenter, this jurisprudence was understood to prohibit essentially unjust or arbitrary discrimination between persons or corporations ''in a similar situation or condition.'' [221]

The commenter next looked at secs. 202(a) and (b) of the Act in the context of the statutory scheme, contrasting their broad reach with the more limited scope of secs. 202(c) through (f), which specifically target business practices with anticompetitive effects, and arguing this difference implies Congress intended for these first two sections to apply more expansively. This commenter further claimed, if unfair, discriminatory, prejudicial, or deceptive conduct always required proof of market-wide competitive injury, these paragraphs would be superfluous because paragraph (e), which prohibits ''any course of business'' or ''any act'' for the purpose or with the effect of causing competitive injury, would always apply. The commenter said this broad interpretation of secs. 202(a) and (b) to include discrimination based on protected-class or market-vulnerable status easily advances the Act's statutory purpose of ensuring fair competition and trade practices in livestock markets, noting that this type of discrimination reduces output and prevents efficient resource allocation by restricting certain producers' ability to enter and participate in markets. The commenter also said legislators enacting the Act sought to broadly address imbalances between buyers and sellers of livestock, referring in detail to the Act's legislative history for evidence that Congress intended for it to have an expansive scope, including coverage of a wide range of unfair and unjust practices.

The commenter also argued that the prohibitions in secs. 202(a) and (b) do not merely include intentionally

[218] *See Wilson & Co.* v. *Benson,* 286 F.2d 891, 895 (7th Cir. 1961); *Bowman* v. *USDA,* 363 F.2d 81, 85 (5th Cir. 1966), *Swift,* 393 F.3d at 253.

[219] Title 9, part 201 of the Code of Federal Regulations (CFR). Section 407 of the P&S Act (7 U.S.C. 228) provides that the Secretary ''may make such rules, regulations, and orders as may be necessary to carry out the provisions of this Act.

[220] 86 FR 36987, July 9, 2021.

[221] *See* 14 Fletcher Cyc. L. Corps. section 6716 (2022). *See also, e.g., Holden* v. *Hardy,* 169 U.S. 366, 383 (1898)); *Yick Wo,* 118 U.S. 356, 373–74; (1886); *San Bernardino Cnty.* v. *S. Pac. R. Co.,* 118 U.S. 417, 422–23 (1886) (Field, J., concurring); *Barbier* v. *Connolly,* 113 U.S. 27, 31 (1884); *C.R. Cases,* 109 U.S. 3, 25 (1883); *In re State Freight Tax,* 82 U.S. 232, 263 (1872).

discriminatory actions but also extend to actions with a disparate impact on covered producers based on their protected-class or market-vulnerable status. To support this position, the commenter noted that sec. 202(a) prohibits regulated entities from engaging in practices or using devices that are ''unjustly discriminatory,'' rather than simply prohibiting them from actively discriminating, and that sec. 202(b) prohibits regulated entities from ''subject[ing]'' persons or localities to undue or unreasonable prejudices or disadvantages, arguing that both provisions specifically use language intended to encompass non-intentional actions.

The commenter further argued that AMS holds authority to interpret the meaning of sec. 202 and identify practices that violate its prohibitions. The commenter said Congress modeled USDA's role under the Act on that of the Federal Trade Commission under the FTC Act, envisioning an authority with broad jurisdiction and power. According to the commenter, Congress even went beyond the FTC Act model in one respect in its grant of authority to USDA, with sec. 407 of the Act giving USDA unequivocal authority to promulgate rules as needed to carry out its provisions. The commenter also said many court decisions have given strong deference to USDA determinations on whether a practice violates the Act, relying on reasoning that the facts of individual cases determine the meaning of the Act's operative terms, and that USDA is responsible for efficiently regulating market agencies and packers. Finally, the commenter argued ''*Chevron* deference'' [222] applies to USDA interpretations of the Act regarding differential treatment because these interpretations would be promulgated pursuant to express delegation of rulemaking authority as given in sec. 407, fill in the gaps Congress left in sec. 202, reflect a permissible construction of the statutory text that aligns with the statute's purpose, and take advantage of USDA expertise regarding the details of livestock production and marketing.

One commenter recommended the following proposed regulatory text language to explicitly state violations of the proposed rule require no showing of competitive harm:

§ 201.308 No Requirement to Cause Market-Wide Harm

Where a regulated entity commits conduct prohibited by Subpart 201.302–201.306, such conduct violates §§ 202(a) and (b) of the Act whether or not market-wide harm to competition results. The unfair, unjustly discriminatory, or deceptive treatment of one covered producer, the giving to one covered producer of an undue or unreasonable preference or advantage, or the subjection of one covered producer to an undue or unreasonable prejudice or disadvantage in any respect violates the Act.

AMS Response: AMS notes and appreciates the comments, but made no further changes in response to the comments.

AMS acknowledges the commentors' comments around a showing of harm to competition. The meaning of competition or harm to competition must be broader than its meaning under the antitrust laws.[223] USDA maintains that this consistently held position is based on the language, structure, purpose, and legislative history of the Act, and USDA continues to adhere to this longstanding position, notwithstanding the disagreement of some courts as to the relationship between harm to competition and violations under the Act. Discrimination and undue prejudice on the bases set forth in this final rule are both essentially unjust and undue as forms of unacceptable personal discrimination under the Act (drawing on similar precedent from the ICA and from P&S Act implementation in stockyards), and also subvert normal market forces, undermine market integrity, and deprive producers of the true value of their products and services. AMS has not incorporated the suggested § 201.308 provisions because the rule itself prohibits discrimination against an individual producer on the prohibited bases or protected activities. The proposed rule elaborated on the regulatory text, stating ''[t]his proposed regulation sets forth specific prohibitions on prejudicial or discriminatory acts or practices against individuals that are sufficient to demonstrate violation of the Act without the need to further establish broad-based, market-wide prejudicial or discriminatory outcomes or harms.'' [224] AMS's position is that under the Act even a single instance of discriminatory or prejudicial conduct may violate the Act.[225] The Act prohibits ''essentially unjust'' discrimination and undue prejudice, which AMS has determined the provisions of this final rule to address. Moreover, discrimination on prohibited bases and retaliation on the basis of protected activities in livestock and poultry markets leads to economic inefficiency, and has no procompetitive justification. Undue prejudices or disadvantages and discriminatory practices in a concentrated livestock or poultry market inflict economic harm through a distortion of market signals such as a distortion of market prices and exclusion of market participants, which, in turn, can lead to disinvestments in the livestock and poultry markets and a misallocation of scarce resources. Deception deprives the seller of the benefits of the market, as competitors of the initial deceiving regulated entity may be induced to likewise engage in such practices. When market abuses become widespread, market success becomes less based on productive efficiency or quality and more on who can engage in the most abuses, leading to allocative inefficiencies and loss of social welfare.

Comment: Commenters representing industry perspectives said proposed § 201.306 on deceptive practices is outside the scope of the Act because it would require all tort or contract disputes under the Act to be addressed in Federal courts rather than as State matters. According to the commenters, Congress would have explicitly said so if it intended to give AMS wide-ranging authority to regulate the specifics of livestock industry contracts and business practices regardless of their effect on competition. According to commenters, further evidence that Congress did not intend to give the agency such authority includes its previous rejections of other proposals to expand the Act to cover contractual matters traditionally covered under State law, with Federal courts likewise holding that the Act does not cover these circumstances.

A cattle industry trade association said this provision also exceeds the scope of the Act because AMS's contention that deception does not

[222] *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 468 U.S. 837 (1984).

[223] Herbert Hovenkamp, ''Does the Packers and Stockyards Act Require Antitrust Harm?'' (2011). Faculty Scholarship at Penn Carey Law. 1862. *https://scholarship.law.upenn.edu/faculty_scholarship/1862;* Peter Carstensen, The Packers and Stockyards Act: A History of Failure to Date, CPI Antitrust Journal 2–7 (April 2010) (''Congress sought to ensure that the practices of buyers and sellers in livestock (and later poultry) markets were fair, reasonable, and transparent. This goal can best be described as market facilitating regulation.''); Michael C. Stumo & Douglas J. O'Brien, ''Antitrust Unfairness vs. Equitable Unfairness in Farmer/Meat Packer Relationships,'' 8 Drake J. Agric. L. 91 (2003); Michael Kades, ''Protecting livestock producers and chicken growers,'' Washington Center for Equitable Growth (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf.*

[224] 87 FR 60018.

[225] Extensively discussed in Michael Kades, ''Protecting livestock producers and chicken growers,'' Washington Center for Equitable Growth (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf,* among other articles referenced above.

require proof of a particularized intent contradicts the plain text of the statute as it would have been interpreted at enactment. According to the commenter, Congress at this time would have understood meatpacker conduct only to be deceptive when committed with the intent to deceive a producer. The commenter further stated that AMS's arguments that deceptive practices under sec. 202 of the Act do not necessarily require intent to deceive—based on analogy to developments in the law of deceptive marketing—do not provide sufficient support for its position. An organization asserted that the proposed rule attempts to undercut Federal court rulings, such as *Jackson* v. *Swift Eckrich, Inc.,*[226] which hold that the Act is not intended to undermine traditional freedom-of-contract principles by exposing producers to Federal liability if they refuse to enter into certain contracts or exercise basic contract rights.

AMS Response: This rule does not require all tort or contract disputes under the Act to be addressed in Federal courts rather than as State matters. It only addresses the specific prohibited conduct covered by the rule. Moreover, in secs. 202(a) and (b), Congress gave broad authority to the Secretary to establish the scope of Federal protections governing transactions in livestock and poultry, given the interstate nature of the industry.

The Act does not require proof of a particularized intent to deceive.[227] This rule does not inhibit freedom to contract by exposing producers to liability if they refuse to enter into a contract.[228] It addresses undue prejudice, retaliation, and deception which may occur at various stages of the contracting process, including the stage when a refusal to deal may amount to discrimination on the bases of prohibited categories specified in the final rule or a deceptive practice when distorted owing to an untrue statement. Therefore, this rule does not contradict the holding in *Jackson* v. *Swift Eckrich, Inc.* Accordingly, AMS made no changes to the rule in response to these comments.

Comment: Cattle industry trade associations argued the proposed rule also represents an inappropriate attempt to regulate commercial feed yards under the Act, saying AMS improperly cites *Solomon Valley Feedlot Inc.* v. *Butz*[229]—a case holding that feed yards are not regulated entities under the Act—to support its reference to surety bonds as one means to protect farmers and consumers from unfair practices under the Act. According to the commenters, AMS's citation in this context suggests commercial feed yards are required to post bonds despite the case holding that they are not regulated entities and thus do not need to do so. A commenter further said this inaccurate citation, combined with the proposed rule's overbroad definition of ''livestock producer,'' suggests AMS is trying to regulate feed yards under the Act despite both Congressional intent and judicial precedent supporting their exclusion.

AMS Response: AMS respectfully considers these comments to be outside the scope of this rulemaking. To be clear, AMS does not intend to refute the court's holding in *Solomon Valley* that feedlots are unregulated. Nor does the rule make any attempt to define ''regulated entities'' to include feedlots.

This final rule prohibits regulated entities from engaging in deceptive practices. Regulated entities include packers, swine contractors, and live poultry dealers. The rule *protects* feedlots as livestock producers from undue prejudice, retaliation, and deception. AMS sees no reason for the commenter's argument that the definition of livestock producers should exclude feedlots, except to the extent that the feedlot is acting as a dealer under the Act. This rule does not attempt to regulate the behavior of livestock dealers or feedlots in any capacity. The *Solomon Valley* decision, which shows it is a deceptive practice for a regulated entity to fail to maintain a bond, was cited in the proposed rule to provide an example of what the court has found constitutes a deceptive practice.

ii. Congressional Direction

Comment: Live poultry dealers and poultry industry trade associations said Congressional authority for AMS to issue the proposed rule has expired because the agency did not promulgate it within the deadline set by the 2008 Farm Bill. A commenter said this Farm Bill included language asking GIPSA, the agency formerly in charge of implementing the Act, to promulgate new regulations dealing with several sections of the Act. The commenter noted that section 11006 of the 2008 Farm Bill tasked AMS with writing new regulations establishing criteria to determine four issues, including whether an undue or unreasonable preference or advantage has occurred in violation of the Act. Section 11006 included a timeline, requiring AMS to promulgate these new regulations no later than two years after the Farm Bill's May 22, 2008, enactment. However, AMS did not publish the proposed rule for comment until October 3, 2022, nearly 12 years after the Farm Bill deadline expired. According to the commenter, finalizing the proposed rule would therefore unconstitutionally exceed the scope of Congress's grant of authority to USDA.

Likewise, a meat industry trade association argued that Congress referred to issues relating to socially disadvantaged farmers and ranchers in other parts of the 2008 Farm Bill but failed to do so in the context of its direction for rulemaking under the Act; therefore, it is reasonable to assume Congress did not seek to address such topics under the Act.

AMS Response: AMS respectfully considers these comments to be outside the scope of this rule. The 2008 Farm Bill's directive that GIPSA promulgate rulemaking pertaining to the Act does not restrict USDA's and AMS's authority to conduct *this* rulemaking and thus effectuate the purposes of the Act.

Further, as noted earlier, Executive Order 14036 directs the Secretary to address unfair treatment of farmers and improve conditions of competition in their markets by considering rulemaking to address, among other things, certain market abuses and anticompetitive practices in the livestock, poultry, and related markets, including unjustly discriminatory, unduly prejudicial, and deceptive practices—in particular retaliation. This final rule is responsive to the Executive Order.

Comment: A cattle industry trade association and a live poultry dealer argued that, in addition to taking advantage of an expired grant of authority, the proposed rule also extends beyond the scope of the original Congressional authority to amend the Act. Commenters said issues not covered under the Farm Bill grant include the introduction of a vague and ambiguous definition of ''market vulnerable individual;'' a determination that proof of anticompetitive harm is no longer necessary to prevail under secs. 202(a) or (b) of the Act; and regulation of deceptive practices and of recordkeeping.

AMS Response: As stated by Congress, the purpose of the Act is ''to assure fair competition and fair trade practices, to safeguard farmers and ranchers . . . to protect consumers . . .

[226] 53 F.3d 1452, 1458 (8th Cir. 1995).

[227] *See Parchman* v. *U.S. Dep't of Agric.,* 852 F.2d 858, 864 (6th Cir. 1988).

[228] *Swift & Co.* v. *United States,* 393 F.2d 247, 253 (7th Cir. 1968).

[229] 550 F. 2d 717 (10th Cir. 1977).

and to protect members of the livestock, meat, and poultry industries from unfair, deceptive, unjustly discriminatory and monopolistic practices. . . .'' This regulation bans behavior that is unjustly discriminatory, unreasonably prejudicial and disadvantageous, and deceptive. AMS has addressed the other matters raised by the commenter in previous comment responses.

Comment: Multiple industry commenters argued that the proposed rule triggers the major questions doctrine under *West Virginia* v. *EPA,* under which an agency lacks authority to take politically or economically significant regulatory actions without ''clear congressional authorization.'' [230] Commenters said the Supreme Court has indicated particular concern where an agency fundamentally changes the regulatory scheme under a statute, seeks to adopt a rule Congress has clearly and repeatedly declined to enact, or claims broad authority for which there is a lack of historical precedent, arguing that the proposed rule raises all three of these issues.[231] Commenters argued that the Act has long been understood to be grounded in antitrust principles and has never in its hundred-year history been used to broadly address the kind of discriminatory conduct covered in the proposed rule. The commenters further claim that the proposed rule's treatment of the Act as an antidiscrimination statute also unprecedently extends past the scope of other such laws by targeting discrimination against independent contractors rather than employees.[232] They also note that, in addition to declining to apply the Act as an antidiscrimination statute, Congress has also declined to adopt any general prohibitions on discrimination in contracting extending beyond the ban on racial discrimination in 42 U.S.C. 1981. The commenters stressed that it would be the role of Congress, not AMS, to decide to apply the Act like an antidiscrimination statute. According to the commenters, specific aspects of the proposed rule that trigger this doctrine include the elimination of the harm-to-competition standard, the creation of a definition of ''market vulnerable individuals,'' the identification of conduct constituting deceptive conduct, and the 5-year document retention mandate for regulated entities.

AMS Response: As discussed in the preamble to this final rule, Congress enacted the Act after many years of concern about farmers and ranchers being cheated and mistreated. In the Act, Congress gave the Secretary broad authority to regulate the meatpacking industry. Congress believed that existing antitrust and market regulatory laws, including the Sherman Act and Federal Trade Commission Act, did not sufficiently protect farmers and ranchers. In the Act, Congress gave the Secretary broad authority to regulate the meatpacking industry. The House of Representatives' report on the Act stated that it was the ''most comprehensive measure and extends farther than any previous law in the regulation of private business, in time of peace, except possibly the interstate commerce act.'' [233] The Conference Report on the Act stated that: ''Congress intends to exercise, in the bill, the fullest control of the packers and stockyards which the Constitution permits. . . .'' [234] Congress considered this a power beyond the authority that of the FTC and the Interstate Commerce Commission.

This rule's interpretations of unjust discrimination, undue and unreasonable prejudice, and retaliation are consistent with longstanding approaches to protecting producers under the Act, are consistent with interpretations of similar provisions of sec. 5 of the FTC Act and the ICA, and mirror congressional policy as reflected in ECOA. Moreover, Congress as recently as 2008 directed USDA to conduct rulemakings on sec. 202, which led to the 2020 Rule discussed above on undue preferences. The 2020 Rule wrestles with questions of undue prejudices which this final rule settles. Deception similarly follows a long line of cases and rules covering deceptive practices under the Act. Regarding issues raised by commenters around the major question doctrine, this rule does not address political matters, nor does it focus on fixing purely economic harms. This rule aims to increase protections for producers by clarifying that secs. 202 (a) and (b) of the Act prohibit discriminatory, retaliatory, and deceptive conduct by regulated entities.

iii. Legal Justification

Comment: Live poultry dealers and industry associations argued that the administrative record for the proposed rule fails to support a rulemaking. Commenters contended AMS has failed to identify any actual harmful conduct that would justify the proposed rule. Several commenters criticized specific aspects of the record, saying the court cases providing examples of alleged violations of the Act seem to be ''opportunistically selected'' and inaccurately cited, while the discussions of previous rulemaking efforts, many of which were withdrawn after Congressional objection, do not provide legitimacy. The commenters said, rather than basing its justification on facts, AMS instead acted arbitrarily and capriciously in supporting it with unverifiable anecdotal evidence and anonymous sources. A cattle industry trade association said that the proposed rule is too reliant on unexplained anecdotal evidence and suggested AMS has compounded this problem by encouraging commenters to respond anonymously.

A commenter said AMS aggravates these issues by inviting more anonymous feedback in its request for comment on the proposed rule, making it difficult to assess commenters' credibility, encouraging more false or unverifiable anecdotes, and further weakening the evidentiary foundation of the eventual final rule. The commenter urged AMS to reopen the comment period after clarifying that it will not give anonymous anecdotes disproportionate weight. Another commenter said, as AMS explicitly left racially discriminatory practices off its list of criteria for finding undue or unreasonable preferences under the Act in promulgating the final rule codified at 9 CFR 201.211,[235] it must explain its rationale for reversing its position to determine that the Act now covers protected-class discrimination.

AMS Response: AMS disagrees with commenters' argument that the administrative record for the proposed rule fails to support this rulemaking. Section 407 of the Act (7 U.S.C. 228) provides that the Secretary ''may make such rules, regulations, and orders as may be necessary to carry out the provisions of this Act.'' Under the APA, an Agency may conduct rulemaking to

[230] *West Virginia* v. *EPA,* 142 S. Ct. 2587, 2613–14 (2022).

[231] *Id.* at 2612, 2610; *NFIB* v. *OSHA,* 142 S. Ct. 661, 666 (2022) (per curiam).

[232] 42 U.S.C. 2000e-2; E.E.O.C., Coverage, *https://www.eeoc.gov/employers/coverage.cfm* (last visited Jan. 1, 2023); see also Health Care Workers and the Americans with Disabilities Act, *https://www.eeoc.gov/laws/guidance/health-care-workers-and-americans-disabilitiesact#:~:text=While%20the%20ADA's%20protections%20apply,does%20not%20cover%20independent20contractors* (last visited Jan. 1, 2023) (''While the ADA's protections apply to applicants and employees, the statute does not cover independent contractors.''); 29 U.S.C. 623; E.E.O.C., Coverage, *https://www.eeoc.gov/employers/coverage-0#:~:text=People%20who%20are%20not%20employed,by%20the%20anti%2Ddiscrimination%20laws* (last visited Jan. 1, 2023) (''People who are not employed by the employer, such as independent contractors, are not covered by the antidiscrimination laws.'').

[233] House Report No. 67–77, at 2 (1921).

[234] House Report No. 67–324, at 3 (1921).

[235] *See* 85 FR 79779.

revise prior positions if it can show that there are ''good reasons'' for the change and that the ''new policy is permissible under the statute.'' [236] AMS gathered evidence from livestock producer and poultry grower testimonies, Congressional testimonies, DOJ and USDA public workshops, case law, and economic data. AMS has gathered economic data on disparities between white farmers and ranchers and other racial and ethnic groups. This data is presented in Figure 5 and highlights the need for this rulemaking to provide fair access to markets for all producers. Preliminary empirical results indicate that there are some systemic differences in prices received across ethnic/racial groups after accounting for regional fixed effects and marketing variables. Relative to White producers, historically underserved Black and American Indian groups receive lower cattle prices; Black groups receive lower contract broiler prices, and Black and American Indian groups receive lower hog prices.[237]

The provisions in this rule are basic, fundamental protections against discrimination on prohibited bases as authorized by the Act and as consistent with congressional policy. The prohibition on retaliation protects the ability for producers to communicate with governmental entities, associate, cooperate, and compete. The prohibitions on deception are equally basic. These basic and fundamental provisions are justified with the record presented. Decades of complaints by producers, include public hearings with the Department of Justice, have catalogued how vertical integration and market concentration have left producers unable to avoid adverse treatment that tends to exclude them from the marketplace, including retaliation preventing them from even reporting these concerns to governmental authorities. The result has been producers unable to bargain effectively in the marketplace or fully obtain the benefits of their livestock production and poultry grow out services. Regulated entities consistently assert they do not engage in such practices; if so, then the burdens from adopting this rule are low.

AMS is not reopening the comment period for this rule. Consistent with the Administrative Procedure Act, all interested persons had an opportunity to comment and the agency has considered all relevant matter received through the public comment process.

AMS does not agree that it has reversed its position with respect to the rationale underpinning the rule promulgating § 201.211. This final rule addresses undue and unreasonable prejudices and disadvantages and unjust discrimination. Conversely, the rule implementing § 201.211 addressed undue and unreasonable preferences and advantages. AMS may return to the question of undue and unreasonable preferences and advantages in future rulemaking but does not have at this time any further information to offer with respect to how AMS would or would not apply the Act's prohibition on undue or unreasonable preferences or advantages. AMS is not making any further changes in response to this comment.

Comment: A cattle industry association said AMS has provided no meaningful evidence of discrimination on grounds other than race, saying evidence of the latter is unnecessary because racial discrimination in private contracting is already prohibited. According to the commenter, AMS also has provided no evidence that would justify its proposal to establish a broad market vulnerable producer approach to discrimination. This commenter also criticized AMS's citation of disparities in farm size and income along racial and ethnic lines. It said the agency confuses correlation and causation by arguing that smaller minority-owned farms necessarily have a harder time competing because of race discrimination when it has merely shown that minority-owned farms tend to be smaller and that any smaller farms tend to face competitive disadvantages compared to larger ones.

AMS Response: The existence of the continued correlation suggests the continued persistence of problems, and accordingly the need for additional clarity regarding the enforcement of the Act. To the extent that the activities covered are already prohibited, then the clarity provided by this rule should place no new burdens on industry with respect to compliance. Additionally, AMS has adopted in its final rule a list of prohibited bases for undue and unreasonable prejudice and disadvantages instead of using the term ''market vulnerable,'' therefore addressing commenters' concerns around the term's broadness.

Recent research conducted by the USDA's Office of the Chief Economist and presented at the American Association for Agricultural Economics [238] suggests that certain ethnic or racial groups may be suffering currently from discrimination by packers in the establishment and/or performance of livestock and poultry contracts. Qualitatively, the research found consistent differences in prices received for livestock (cattle and hogs) and broiler products across ethnic or racial groups after controlling for variables such as farm size, regional differences, type of marketing contract or channel, organic certification status, distance to closest packer, and size of closest packer. Limitations of the study include that it is unable to control for all animal characteristics and cannot separate disparate economic outcomes arising from current racial discrimination from disparate economic outcomes due to historical discrimination.

Comment: A cattle industry association said the proposed rule is arbitrary and capricious because AMS has yet to release several related proposals dealing with rulemakings under the Act. The commenter notes that sec. 553(c) of the Administrative Procedure Act requires agencies to give interested parties a ''reasonable'' and ''meaningful'' opportunity to participate in the rulemaking, then argues that AMS's failure to disclose how this proposed rule will fit in with other related rules addressing poultry and livestock contractors under the Act does not meet this standard because it does not give parties a chance to respond to the rulemaking actions as a whole.

AMS Response: That previous rulemaking efforts, such as those published in 2016, tied multiple rulemakings together with respect to certain assumptions in their cost-benefit analysis is not dispositive on how this set of rulemakings—which are entirely different and unconnected to the 2016 effort—should be designed or presented for public comment. This final rule is a logical outgrowth of the rule as proposed and does not in any way depend upon what AMS may or may not propose or finalize in any other rules. AMS made no changes to the rule based on this comment.

Comment: A meat industry trade association expressed concern because AMS stated in the preamble to the proposed rule that retaliation may include activities other than those listed in the proposal. The commenter said the statement in the preamble, which says

[236] *FCC* v. *Fox Television Stations,* 556 U.S. 502, 514 (2009).

[237] ''Competition and Discrimination—is there is a relationship between livestock prices received and whether the grower is in a historically underserved group?'' 2023 AAEA Annual Meeting, Washington, DC, July 23–July 25, 2023.

[238] Breneman, V., Cooper, J. Nemec Boeme, R. and Kohl, M. ''Competition and Discrimination—is there is a relationship between livestock prices received and whether the grower is in a historically underserved group?'' 2023 AAEA Annual Meeting, Washington, DC, July 23–July 25.

the proposed rule is ''designed to prohibit all such actions with an adverse impact on a covered producer,'' [239] conflicts with another statement in the preamble regarding § 201.304(b), which says the proposed regulations are ''narrowly tailored, requiring the adverse action to be linked to specific protected activities,'' [240] making the rule arbitrary and capricious in failing to give useful guidance on permissible activities.

AMS Response: The commenter confuses the design of the rule. The specific protected activities set forth under § 201.304(b)(1) and (2) are narrowly tailored and limited to those delineated. In contrast, the forms of adverse conduct, as set forth in 201.304(b)(3), are inherently broader and more flexible. Additionally, the final rule provides greater specificity with respect to forms of adverse conduct, which are now delineated specifically and are no longer subject to open-ended addition.

Therefore, AMS will not make changes to the final rule in response to this comment.

iv. Vagueness

Comment: Commenters argued that multiple provisions of the proposed rule are so vague and open-ended they thwart processors' ability to determine how it may apply to their conduct. According to the commenters, these provisions raise issues under the Fifth Amendment's Due Process Clause, which requires rules of law to define unlawful conduct with enough specificity to let interested parties understand what conduct is prohibited and to prevent arbitrary or discriminatory application of the rule.[241]

Live poultry dealers and a poultry industry trade association said the proposed rule is unconstitutionally vague because it includes a number of poorly defined or undefined terms for which failure to comply would result in a regulatory violation. The commenters said it provides only examples of behavior that would constitute a prohibited ''prejudice or disadvantage'' or ''retaliation,'' rather than spelling out definitive lists or definitions that regulated entities can use to comply with the proposed rule. The commenters highlighted other terms raising vagueness issues, such as ''generally or ordinarily offered,'' ''differential contract performance or enforcement,'' and ''tak[ing] an adverse action.'' These commenters said the rule also fails to spell out other concepts essential for identifying unlawful conduct, such as what would constitute a prohibited pretext or a legitimate explanation, how the recordkeeping requirements would be triggered, or what records must be kept. Commenters emphasized clear definitions are critical for companies to know what is and is not allowed under the rule.

AMS Response: The Due Process Clause under the Fifth Amendment requires legal matters to be resolved according to established rules and principles. AMS has adequately described the type of conduct prohibited under this rule by expressly stating that prejudices on specified prohibited bases constitutes a violation under the Act. These prohibited bases expressly draw from ECOA and apply to the Act and are explained in this rule with the specificity required to give notice to interested parties as to what conduct is prohibited. Moreover, changes in this final rule more clearly delineate prohibited bases of discrimination in § 201.304(a)(1), prohibited prejudicial conduct under § 201.304(a)(2), prohibited retaliatory conduct under § 201.304(b)(3), and more. Concerns of vagueness are addressed by AMS further explaining terms in the final rule with the specificity needed to thwart claims of unconstitutional government action. The final rule also provides two new specific exceptions that address commenters' concerns regarding the proposed rule not including exceptions. Furthermore, as explained in response to earlier comments, the recordkeeping requirement is clear and specific in its explanation in requiring regulated entities to keep certain records pertaining to their business practices relating to activities subject to the jurisdiction of the Act.

The terms used in this rule are intended to follow their plain language meaning, as applied to the livestock and poultry industries and within the legal framework regulating these industries. The following discussion demonstrates how these terms support the rule's prohibitions against undue prejudice, deception, and retaliation and in fact are quite specific.

''Retaliation'' is set forth in paragraph (b)(3) and encompasses actions taken by regulated entities against covered producers such as contract termination, refusal to renew a contract, offering of more unfavorable contract terms than those generally or ordinarily offered, refusal to deal, interference with third-party contracts, and modification of contracts on less favorable terms than those previously enjoyed in response to the producer's participation in a protective activity. What constitutes retaliation is clearly defined in the rule, and likewise the rule clearly lays out protected activities against which retaliation is prohibited.

In this rule, ''generally or ordinarily offered'' terms are terms most producers would qualify for when contracting with a regulated entity. Whether terms are ''generally or ordinarily offered'' is an inquiry regarding specific facts and circumstances. Each case may vary by regulated entity and even for any given regulated entity may vary based on how the regulated entity would normally deal in the circumstances presented by the producer in question. However, ''generally or ordinarily'' does not apply to special contract terms that some regulated entities may use with certain producers, whether to receive particular quality attributes or services or for other reasons that are not discrimination on prohibited bases. The purpose of the rule is to ensure that a covered producer is not denied contract terms on the basis of a protected class that an ''ordinary'' similarly situated producer could receive from the regulated entity.

''Performing under or forcing a contract differently than with similarly situated producers'' refers to situations where a regulated entity operates in such a way that it denies a grower the full benefits to which it is entitled under its contract with the regulated entity. A poultry grower may seek to enforce a production contract term that gives the grower the right to receive appropriate feed for the grower's flocks on a timely basis in the event the grower regularly or at critical times experiences insufficient, delayed, or inappropriate feed. If a regulated entity threatens to terminate a grower's contract in response to the grower's efforts to enforce a particular contract term (a protected activity), this retaliatory conduct would violate the Act. AMS notes that this violation would be separate from any violation of contract law that may also exist. Another example is selective information disclosures. These often take the form of a regulated entity withholding materially relevant information from one covered producer that the regulated entity generally or ordinarily provides to other covered producers. In these instances, information-deprived producers will have an incomplete picture of their business relationships with regulated entities, and therefore will operate at an unreasonable disadvantage relative to producers who receive the pertinent information.

[239] 87 FR 60026, October 3, 2022.

[240] *Id.* at 60024.

[241] See *Skilling* v. *United States,* 130 S. Ct. 2896, 2927–28 (2010).

Furthermore, this rule not only protects covered producers from such conduct in the form of retaliation. If a regulated entity engages in differential contract enforcement on the bases of a producer's protected class, this would constitute discriminatory conduct in violation of § 201.304(a) of this regulation.

''Tak[ing] an adverse action'' encompasses a range of prejudicial, deceptive, or retaliatory actions that unjustly inhibit market access such as prejudice, disadvantage, retaliation, deception, or any action that inhibits market access to producers. A range of actions taken by producers on legitimate business grounds can be adverse to producer welfare. However, in the context of this rule, adverse actions are those actions taken by regulated entities against producers that either unfairly discriminate against producers on the basis of a protected class, deceive producers, or represent retaliation against producers for engaging in protected activities such as lawful communications, assertion of contract rights, associational participation, or participating as a witness in any proceeding under the Act.

v. Other Legal Issues

Comment: A cattle industry trade association said the requirement to demonstrate harm to competition is crucial within its industry because packers differentiate cattle values using an array of different factors including production method, animal handling requirements, and program enrollment, meaning that seemingly similar lots of cattle may be valued substantially differently. The commenter expressed concern that the results of individual adjudications taking place under sec. 202 of the Act without the threshold of a competitive-injury requirement would vary significantly, diminishing innovation and product differentiation, confusing market participants, and ultimately harming both producers and consumers. A poultry industry trade association said that, if AMS seeks to establish circumstances in which conduct can violate secs. 202(a) and (b) without a showing of competitive injury, a separate standalone rulemaking would be more suitable than inclusion in the proposed rule.

AMS Response: This final rule solely addresses the prohibited conduct it covers—undue prejudice on prohibited bases, retaliation as unjust discrimination for engaging in protected activities, and certain forms of deception. It does not, beyond the specific prohibitions, interfere with the manner in which packers differentiate cattle values using an array of different factors including production method, animal handling requirements, and program enrollment, meaning that seemingly similar lots of cattle may be valued substantially differently. Individual adjudications with respect to the conduct covered by this proposed rule are essential to effectuate the prohibitions set forth in this rule, so as to eliminate in their incipiency occurrences of undue prejudice on prohibited bases and retaliation on protected activities.[242] The Act empowers the Secretary to make the determinations around what conduct is unreasonable and undue prejudices and disadvantages and unjust discrimination. It is also well-established that deception is a prohibition that can be enforced on the bases of each individual occurrence.

Moreover, even where relevant, the meaning of competition or harm to competition must be broader than its meaning under the antitrust laws.[243] USDA has previously explained that this consistently held position is based on the language, structure, purpose, and legislative history of the Act, and USDA continues to adhere to this longstanding position, despite the disagreement of some courts as to the relationship between harm to competition and violations under the Act. *See* Scope of Sections 202(a) and (b) of the Packers and Stockyards Act, 82 FR 48596 (Oct. 18, 2017), (reaffirming that ''USDA has adhered to this interpretation of the P&S Act for decades'' and rejecting comments that this interpretation is not the USDA's longstanding position). Regardless, even if a showing of harm to competition were required for an undue prejudice or discrimination claim, the discriminatory practices prohibited in this rule would meet such a requirement. Discrimination and undue prejudice have no value or place in a competitive market, and in fact can lead to inefficiencies as personal characteristics, not production factors influence contracting decisions. Ultimately, the conduct at issue is squarely within the purposes of the Act. Where conduct ''prevents an honest give and take in the market,'' it ''deprives market participants of the benefits of competition'' and ''impedes . . . a well-functioning market.'' In its report on the 1958 amendments to the Act, the U.S. House of Representatives explained that the statute promotes both ''fair competition and fair trade'' and is designed to guard ''against [producers] receiving less than the true market value of their livestock.'' Discrimination and undue prejudice on the bases set forth in this final rule are both essentially unjust and undue as forms of unacceptable personal discrimination under the Act (drawing on similar precedent from the ICA and from P&S Act implementation in stockyards), and also subvert normal market forces, undermine market integrity, and deprive producers of the true value of their products and services.

Comment: A legal foundation said the introduction of a recordkeeping requirement for processors may violate the due process clause by imposing unreasonable burdens on them and may exceed the limits of Federal enumerated powers under the Constitution. The commenter said that, although the Supreme Court upheld a recordkeeping requirement for banks against a due process challenge, the ruling was specific to entities receiving public funds and does not apply to regulated entities under the proposed rule. The commenter also contended such recordkeeping requirements generally lead to warrantless searches of businesses, and that these types of searches are only authorized for pervasively regulated, inherently hazardous industries, which likely does not apply to the meat or poultry industries.

AMS Response: AMS has authority under the Act to regulate certain entities and to promulgate rulemaking accordingly. The inclusion of a recordkeeping requirements serves the legitimate purpose to ensure compliance with this rule. Recordkeeping is regularly a component of rulemaking to ensure compliance and allow the regulating agency to better monitor impacts of the Rule. Regulated entities are already subject to a range of oversight by AMS subject to the longstanding application of the Act. Indeed, the Act already requires recordkeeping that fully and completely discloses the transactions by regulated entities of their poultry growing arrangements and transactions in

[242] *Bowman* v. *United States Dep't of Agric.,* 363 F.2d 81, 85 (5th Cir. 1966)

[243] Herbert Hovenkamp, ''Does the Packers and Stockyards Act Require Antitrust Harm?'' (2011). Faculty Scholarship at Penn Carey Law. 1862. *https://scholarship.law.upenn.edu/faculty_scholarship/1862;* Peter Carstensen, The Packers and Stockyards Act: A History of Failure to Date, CPI Antitrust Journal 2–7 (April 2010) (''Congress sought to ensure that the practices of buyers and sellers in livestock (and later poultry) markets were fair, reasonable, and transparent. This goal can best be described as market facilitating regulation.''); Michael C. Stumo & Douglas J. O'Brien, ''Antitrust Unfairness vs. Equitable Unfairness in Farmer/Meat Packer Relationships,'' 8 Drake J. Agric. L. 91 (2003); Michael Kades, ''Protecting livestock producers and chicken growers,'' Washington Center for Equitable Growth (May 2022), *https://equitablegrowth.org/wp-content/uploads/2022/05/050522-packers-stockyards-report.pdf.*

livestock, meat, live poultry, etc.[244] The recordkeeping addressed by this rule is to keep records already kept, and is within the scope of AMS's authority under the Act.[245]

Comment: A cattle industry trade association said AMS failed to clarify the causation standards for proving a violation of its new discrimination rule. The commenter suggested AMS should confirm that the default causation rule under tort law applies, meaning a violation would require impermissible discrimination to be the but-for cause of a packer's contracting decision.

AMS Response: Although pervasive unjust discrimination has in the past kept outstanding producers from achieving their potential, AMS recognizes that adverse actions against producers commonly have several elements mixed in, some of which may include the discrimination or retaliation covered by this rule. AMS has set forth a standard causation standard: ''because'' and ''on the basis of.'' Further cause will be determined in the specific facts and circumstances of any enforcement matter. Those facts will determine whether AMS brings any particular matters and AMS expects unjust discrimination and retaliation to be the principal, or at least substantial, part of any decision by the regulated entity. Moreover, AMS is choosing not to require ''sole'' causation because doing so would undermine the effectiveness of the rule and encourage after-the-fact revisions of causation. Rather, AMS believes that regulated entities should have a heightened duty to eliminate unjust discrimination on the protected basis and retaliation for engaging in protected activities. To do so, boards of directors and chief executive officers may wish to establish clear corporate policies, adopt procedures to provide for heightened managerial supervision for circumstances where a close call may arise, and implement training across the corporate structure. ''Tone at the top'' should direct employees such that undue prejudice and retaliation are not acceptable forms of conduct, and when close calls arise, the regulated entity has taken every step reasonably possible to ensure that its conduct is focused solely on the merits of the producer's performance and the other competitive factors that the regulated entity must take into account when running its business. AMS made no changes to the final rule based on this comment.

L. Other Comments Related to the Proposed Rule

Comment: A cattle industry trade association said that AMS has not yet made available its proposal for an additional related rule concerning section 202 of the Act, which must be considered alongside the current proposal. A meat industry trade association likewise cited AMS's anticipation of a ''suite of major actions [. . .] to create fairer marketplaces for poultry, livestock and hog producers'' and argued that AMS should withdraw the current proposal until the entire suite of proposals can be submitted holistically. Live poultry dealers and industry companies, a poultry industry trade association, and a swine industry trade association concurred that piecemeal updates to the Act would create challenges and confusion for regulated entities and producers. They suggested updating regulations collectively at one time.

AMS Response: AMS made no changes to the proposed regulations based on this comment. AMS appreciates the comments regarding the desire to view the rules holistically. However, AMS is under no obligation to make all potential rules available to the public simultaneously, regardless of their potential connection to components of this rulemaking. AMS is addressing issues in the livestock and poultry sector through its statutorily defined authority to administer the Act. Federal agencies commonly use separate rulemakings to address specific issues under their regulatory authority. As stated elsewhere, the authority or effect of this rule does not in any way depend upon the proposal or adoption of any other rules, proposed or not yet proposed. Accordingly, AMS made no changes based on this comment.

Comment: A cattle industry trade association noted that the proposed rule's preamble implied a strong relationship between concentration in the meatpacking industry and declining use of negotiated cash trades, with the further implication that the use of AMAs in place of cash trades has negatively impacted the market and rural economies. The commenter said that AMAs are not germane to the proposed rule and requested information on whether AMS intends the proposed rule to limit the ability of cattle producers to use AMAs. It argued that AMAs are critical to funding production of more sustainable and climate-friendly cattle production. In defense of AMAs, the trade association cited a 2021 Texas A&M study finding that AMAs do not change underlying supply-and-demand fundamentals and so do not create market power[246] and a 2007 GIPSA Livestock and Meat Marketing Study finding a negative effect on producer and consumer surplus measures in response to reducing AMA use.[247] Another cattle industry trade association agreed that AMAs benefit producers and cautioned against any attempts to standardize agreements between producers and regulated entities through new rules.

AMS Response: AMS acknowledges the commenters' concerns over the relationship between this rulemaking and the use of AMAs in the cattle industry. According to some in the industry, the growth of these vertical contracting relationships in the context of highly concentrated markets has led to concerns that firms have greater control over producers and thus have more ability to abuse their market power, impede producer choices, exclude some market participants, and coerce producers unwittingly into inefficient farm decisions. This rule prohibits prejudices on certain protected bases that tend to exclude or disadvantage covered producers in those markets; identifies retaliatory practices that interfere with lawful communications, assertion of rights, and associational participation, among other protected activities, as unjust discrimination prohibited by the law; and identifies deceptive practices that violate the Act with respect to contract formation, contract performance, contract termination, and contract refusal. AMS sees no manner in which this regulation affects the general existence or use of AMAs. Therefore, AMS has made no changes to the regulations in response to this comment.

Comment: An industry company rejected any implication that food companies are withholding critical business information from producers

[244] Section 401 of the Act requires regulated entities to keep ''such accounts, records, and memoranda as fully and correctly disclose all transactions involved in his business . . .'' Section 201.94 of the regulations requires regulated entities to give the Secretary ''any information concerning the business . . .'' Section 201.95 of the regulations requires that regulated entities provide authorized representatives of the Secretary access to their plaice of business to examine records pertaining to the business. Section 203.4 of the regulations is a Statement of General Policy regarding disposition of records by regulated entities that records be retained for a period of two full years. We have interpreted this to mean that records should be maintained for the current year to date, plus the prior two full years (Jan–Dec). This regulation also provides that longer retention periods may be required upon notice by the Administrator.

[245] *Id.*

[246] Fischer, Bart, L., Joe L. Outlaw, and David P. Anderson, eds. *The U.S. Beef Supply Chain: Issues and Challenges.* Texas A&M University (June 2021) available at *https://www.afpc.tamu.edu/research/publications/710/cattle.pdf.*

[247] *GIPSA Livestock and Meat Marketing Study, Vol. 1,* ES–8 (January 2007).

and argued that producers are already provided critical information required to make informed business decisions. It suggested that, in lieu of new rules to require greater information disclosure, AMS should consider dedicated producer education resources or outreach programs to raise producer awareness.

AMS Response: AMS appreciates this commenter's suggestion to further educate producers and will take this under consideration as additional support AMS may offer to producers. This rulemaking action clarifies that if regulated entities make omission of material information necessary to make a statement or representation not false or misleading (as defined in the rule) against a covered producer, such conduct amounts to deception and is a violation of the Act. The codification of these regulations stems from existing law that aims to prohibit deception in Act-regulated markets. The new regulations do not create any specific disclosure of information requirements. To the extent that regulated entities identify the need to provide additional information to producers, the facts and circumstances of the transaction will determine whether the information is in violation of the rule. AMS agrees that producer education and outreach are valuable to protecting producers and effectuating the purpose of the Act and intends to conduct more of such activities in the immediate term. AMS is making no changes to the regulations as proposed in response to this comment.

VIII. Regulatory Analysis

A. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This final rule includes a new collection of information contained in new § 201.304(c), ''Recordkeeping of compliance practices.'' The proposed rule requested comment on the estimated recordkeeping burden. All comments received on this information collection are summarized and included in the final request for OMB approval. Under the final rule, there are no new regulatory text changes that would change the proposed rule costs and benefits analyses. The burden estimates under the final rule are updated to reflect the most recent data available, updates in regulated entity wages, and the number of regulated entities. The estimated burden for the recordkeeping requirement imposed by this final rule is as follows:

OMB Number: 0581–NEW.

Expiration Date of Approval: This is a NEW collection.

Type of Request: Approval of a New Information Collection.

Abstract: Section 201.304(c) will require live poultry dealers, swine contractors, and packers to retain all relevant records relating to their compliance with § 201.304(a) and (b) for no less than five years. This recordkeeping requirement is necessary to evaluate compliance with § 201.304(a) and (b) and to facilitate investigations and enforcements based on producer and grower complaints. This recordkeeping requirement will bolster AMS's ability to review the records of regulated entities during compliance reviews and investigations based on complaints of undue prejudices, unjust discrimination, and retaliation in the livestock and poultry industries in accordance with the purposes of the Act. Costs of recordkeeping include maintaining and updating records by regulated entities and will be discussed and quantified below.

Live Poultry Dealer, Swine Contractor, and Packer Recordkeeping Costs

Estimate of Burden: The burden for maintaining records for this information collection is estimated to average 4.25 hours per respondent in the first year, and 3.50 hours annually thereafter.

Respondents: Live poultry dealers, swine contractors, and packers.

Estimated Number of Respondents: 1,030.

Estimated Total Annual Burden on Respondents: 4,377 hours in the first year and 3,605 hours annually thereafter.

Information Collection and Recordkeeping Costs of § 201.304(c): Costs to comply with the recordkeeping are likely relatively low. This rule extends the disposal date of most records, if already kept, from 2 years to five years to promote efficient USDA monitoring efforts. For some records, the current disposal date is 1 year, which could be extended to five years under this rule if they are deemed relevant to showing compliance with this rule. Costs of recordkeeping include regulated entities maintaining and updating compliance records they already keep. From the perspective of the regulated entity, recordkeeping is a direct cost. Some smaller regulated entities that currently do not maintain records may voluntarily decide to develop formal policies, procedures, training, etc., to comply with the rule and will then have records to maintain.

AMS expects the recordkeeping costs will be comprised of the time required by regulated entities to store and maintain records they already keep. AMS expects that the costs will be relatively small because some packers, live poultry dealers, and swine contractors may currently have few records concerning policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, board of directors' oversight materials, and the number and nature of complaints received related to unduly prejudicial and unjustly discriminatory treatment. Some firms might not have any records to store. Others already store the records and may have no new costs.

The amount of time required to keep records was estimated by AMS subject matter experts. These experts were auditors and supervisors with many years of experience in AMS's PSD conducting investigations and compliance reviews of regulated entities. AMS used the May 2022 U.S. Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics for the time values in this analysis.[248] BLS estimated an average hourly wage for general and operations managers in animal slaughtering and processing to be $61.24. The average hourly wage for lawyers in food manufacturing was $103.81. In applying the cost estimates, AMS marked-up the wages by 41.79 percent to account for fringe benefits.

AMS expects that recordkeeping costs will be correlated with the size of the firms. AMS ranked packers, live poultry dealers, and swine contractors by size and grouped them into quartiles, estimating more recordkeeping time for the largest entities in the first quartile than for the smallest entities in the fourth quartile. The first quartile contains the largest 25 percent of entities, and the fourth quartile contains the smallest 25 percent of entities. AMS estimated that § 201.304(c) will require an average of 4.00 hours of administrative assistant time, 1.50 hours of time each from managers, attorneys, and information technology staff for packers, live poultry dealers, and swine contractors in the first quartile to setup and maintain the required records in the

[248] Estimates are available at U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics, available at *https://www.bls.gov/oes/special-requests/oesm22all.zip* (accessed 7/14/2023). Featured OES Searchable Databases: U.S. Bureau of Labor Statistics (*bls.gov*) (accessed July 2023).

first year. AMS expects the packers, live poultry dealers, and swine contractors in the second quartile will require an average of 2.00 hours of administrative assistant time, 0.75 hours of time each from managers, attorneys, and information technology staff for first year costs. The third quartile will require 1.33 hours of administrative assistant time, 0.50 hours of time each from managers, attorneys, and information technology staff for first year costs, and the fourth quartile will require 0.67 hours of administrative assistant time, 0.25 hours of time each from managers, attorneys, and information technology staff.

AMS also expects that packers, live poultry dealers, and swine contractors will incur continuing recordkeeping costs in each successive year. AMS estimated that § 201.304(c) will require an average of 3.00 hours of administrative assistant time, 1.50 hours of time each from managers, attorneys, and 1.00 hour of time from information technology staff for packers, live poultry dealers, and swine contractors in the first quartile to setup and maintain the required records in each succeeding year. AMS expects that packers, live poultry dealers, and swine contractors in the second quartile will require an average of 1.50 hours of administrative assistant time, 0.75 hours of time each from managers, attorneys, and 0.50 hours of time from information technology staff in each succeeding year. The third quartile will require 1.00 hour of administrative assistant time, 0.50 hours of time each from managers, attorneys, and 0.33 hours of time from information technology staff in each succeeding year, and the fourth quartile will require 0.50 hours of administrative assistant time, 0.25 hours of time each from managers, and attorneys, and 0.17 hours from information technology staff.

Estimated first-year costs for recordkeeping requirements in § 201.304(c) totaled $30,000 for live poultry dealers,[249] $193,000 for swine contractors,[250] and $122,000 for packers.[251] Estimated yearly continuing costs for recordkeeping requirements in § 201.304(c) totaled $26,000 for live poultry dealers,[252] $166,000 for swine contractors,[253] and $106,000 for packers.[254]

Breaking out costs by market, AMS expects recordkeeping requirements in § 201.304(c) to cost beef packers $58,000 in the first year and $50,000 in each following year. Section 201.304(c) will cost lamb packers $23,000 in the first year and $20,000 in successive years. Section 201.304(c) will cost pork packers $42,000, and it will cost swine contractors $193,000 for a total of $235,000 in the first year. Section 201.304(c) will cost swine contractors $166,000 in successive years, and it will cost pork packers $36,000 for a total of $202,000 in successive years.

B. Executive Orders 12866, 13563, and 14094; Regulatory Impact Analysis; and the Regulatory Flexibility Act

AMS prepared this assessment in compliance with the requirements of Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means.

This rulemaking has been determined to be significant for the purposes of E.O. 12866 as amended by E.O. 14094 and, therefore, has been reviewed by OMB. As a required part of the regulatory process, AMS prepared an economic analysis of the costs and benefits of §§ 201.302, 201.304, 201.306, and 201.390.

This Regulatory Impact Analysis (RIA) presents an assessment of the anticipated benefits and costs from the rule including an assessment of regulatory alternatives: the *status quo,* the preferred alternative, and the small business exemption alternative. The Regulatory Flexibility Analysis (RFA) evaluates the effect of the rule on small businesses.

This regulatory filing is comprised of definitions in § 201.302, specific prohibited discriminatory and unduly prejudicial practices in § 201.304, specific prohibited deceptive practices in § 201.306, and a statement of severability among the provisions in § 201.390. The definitions in § 201.302 of a covered producer, livestock producer, and regulated entity will apply to §§ 201.304 and 201.306, and the regulatory impacts of the definitions are captured in the regulatory impacts of §§ 201.304 and 201.306, which are highlighted in this analysis.

The statement of severability in § 201.390 has no quantified regulatory impact, as it only serves to ensure that if any provision of §§ 201.302, 201.304, or 201.306 is declared invalid or the applicability to any person or circumstance is invalid, the remainder of the provisions will remain valid.

Under the final rule, there are no new regulatory text changes that would change the proposed rule costs and benefits of the regulatory analyses. The new information collection and recordkeeping requirements under the final rule are updated to reflect only the most recent data available, updates in regulated entity wages and number of regulated entities.

The Need for the Rule: Market Failure in Livestock and Poultry Markets

This section describes the need for the regulatory action, and how the regulatory action will meet this need. The structure of the livestock and poultry industries sets the stage for unjustly discriminatory and deceitful conduct by regulated entities. This rule aims to benefit covered producers by protecting their rights from these market harms. This regulatory action addresses market failure in the livestock and

[249] 90 live poultry dealers × ($44.51 per hour admin. cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost × (1.5 hours + .75 hours + .5 hours + .25 hours))/4 = $30,132.

[250] 575 swine contractors × ($44.51 per hour admin. cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost × (1.5 hours + .75 hours + .5 hours + .25 hours))/4 = $192,507.

[251] 365 packers × ($44.51 per hour admin. cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost × (1.5 hours + .75 hours + .5 hours + .25 hours))/4 = $122,200.

[252] 90 live poultry dealers × ($44.51 per hour admin. cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours))/4 = $26,021.

[253] 575 swine contractors × ($44.51 per hour admin. cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours))/4 = $166,244.

[254] 365 packers × ($44.51 per hour admin. cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours))/4 = $105,529.

poultry industries. This section will show how high levels of concentration, the prevalence of vertical contracting, asymmetry of information and the hold-up problem together create an environment facilitating abusive conduct that this rule addresses and defines the need for this rule. Discriminatory practices are the exclusionary or adverse treatment which market concentration and vertical contracting makes possible and hard to avoid on the basis of a covered producer's race, or other protected basis, and on the basis of actions that prejudice, disadvantage, inhibit market access, or are otherwise adverse compared to terms generally or ordinarily offered to similarly situation covered producers. This rule focuses on prohibiting regulated entities from wrongfully excluding producers from markets or denying those producers the full value of their products or services in those markets. It will then be shown how the livestock and poultry market structures help define the distribution of this rule's costs and benefits.

The Need for the Rule: Prevalence of Concentration and Contracting in Cattle, Hog, and Poultry Industries

The rise of concentration and vertical contracts in livestock and poultry markets has increasingly created an environment that enables packers, swine contractors, and live poultry dealers to unjustly exclude many producers from, and otherwise undermine their economic opportunities in, the marketplace. This adverse treatment is a cost, or economic harm, to covered producers born from market exclusion and associated high search costs of finding alternative markets in concentrated markets coordinated with vertical contracts.

Concentration in these markets has intensified over the past several decades and continues today. Concentration ratios are one metric to track the increasing share of slaughter of livestock and poultry in U.S. attributed to fewer packers and poultry integrators. Table 1 in the *Background* section shows the level of concentration in the livestock and poultry slaughtering industries for 1980–2020 using four-firm Concentration Ratios (CR4). The CR4 for steers and heifers was 36 percent in 1980 and rose to 81 percent in 2020. That is, in 2020, the top four beef packers slaughtered 81 percent of the nation's steers and heifers. The CR4 for hogs was 32 percent in 1980 and rose to 64 in 2020, and the CR4 was 32 percent in 1980 for broilers and rose to 53 percent in 2020.[255]

The data in Table 1 are estimates of CR4s at the national level; however, in practice, the relevant economic markets for livestock and poultry may be regional or local, where concentration may be higher than those at the national level. This is because of limits on how far live animals can be safely and efficiently transported. In particular, regional concentration is often higher than national concentration for hogs.[256] Similarly, based on AMS's experience conducting investigations and monitoring cattle markets, there are often only one or two cattle buyers in many local geographic markets, and very few sellers have the option of selling fed cattle to more than three or four packers. Likewise, even though poultry markets are the least concentrated of the four markets described above as measured by their national CR4s, relevant markets for poultry growing services are more localized than markets for fed cattle or hogs, and local concentration in poultry markets is often greater than the national concentration level. Thus, the current environment is one where producers have little choice in whom they do business with, resulting in an unequal distribution of bargaining power between parties. MacDonald and Key found that about one quarter of contract growers reported that there was just one live poultry dealer in their area, defined by a roughly 34-mile radius from their farm; another quarter reported two; another quarter reported three; and the rest reported four or more.[257] Table 2 in the *Background* section [258] highlights this issue by using the Herfindahl-Hirschman Index (HHI) to show the limited ability of poultry growers to switch to different integrators. Similar to a CR4, HHI is an indicator of market concentration, with the index increasing as market shares across firms (packers) become more unequal or the number of these firms decrease. Markets with HHIs above 2,500 are considered highly concentrated. Table 2 presented earlier from MacDonald showed that 88.4 percent of growers face an integrator HHI of at least 2,500. As stated earlier, the data suggest that most contract broiler growers in the U.S. are thus in markets where the sellers have the potential for market power advantage. Livestock producers face similar market vulnerabilities as shown here for poultry growers given that livestock producers also face regional market concentration that is more concentrated than national data would indicate.

Market concentration and the use of vertical contracts are interrelated; as such, growing, production, and marketing contracts feature prominently in the livestock and poultry industries. As outlined above, several provisions in §§ 201.304 and 201.306 will affect the process of contract formation, performance, termination, and any other action that a reasonable covered producer would find materially adverse for livestock, poultry, and meat grown or marketed.

The type of contracting varies among cattle, hogs, and poultry. Broilers, the largest segment of poultry, are almost exclusively grown under production contracts, in which the live poultry dealers, a regulated entity, own the birds and provide poultry growers with feed and medication to raise and care for the birds until they reach the desired market size. Poultry growers provide the housing, the skill and labor, water, electricity, fuel, and provide for waste removal. Fed cattle marketing contracts typically take the form of marketing agreements. Hog production falls between these two extremes.

As shown in Table 5 below, over 96 percent of all broilers and over 42 percent of all hogs are grown under contractual arrangements. Similar to poultry contracts, swine contractors typically own the slaughter hogs and sell the finished hogs to pork packers. The swine contractors typically provide feed and medication to the swine production contract growers who own the growing facilities and provide growing services. The following table shows that the percentage of contract growing arrangements by species has remained relatively stable between 2007 and 2017.

[255] Sheep and turkeys exhibit similar increases in concentration between 1980 and 2020.

[256] Wise, T.A., S.E. Trist. ''Buyer Power in U.S. Hog Markets: A Critical Review of the Literature,'' *Tufts University, Global Development and Environment Institute (GDAE)* Working Paper No. 10–04, August 2010, available at *https://sites.tufts.edu/gdae/files/2020/03/10-04HogBuyerPower.pdf.TAbl* (last accessed 8/9/2022).

[257] MacDonald, James M. ''Technology, Organization, and Financial Performance in U.S. Broiler Production,'' *EIB–126,* U.S. Department of Agriculture, Economic Research Service, June 2014. (In the 2011 Agricultural Resource Management Survey (ARMS), the mean distance from a grower to the integrator's processing plant was 34 miles, and 90 percent of all birds were produced on farms within 60 miles of the plant.)

[258] MacDonald, James M., and Nigel Key. ''Market power in poultry production contracting? Evidence from a farm survey.'' *Journal of Agricultural and Applied Economics* 44, no. 4 (2012): 477–490.

Table 5: Percentage of Poultry and Hogs Raised and Delivered Under Production Contracts[259]

Species	2007	2012	2017
Broilers	96.5	96.4	96.3
Turkeys	67.7	68.5	69.5
Hogs	43.3	43.5	42.4

Other types of contracts include marketing agreements and forward contracts. Under marketing agreements and forward contracts, producers and packers agree to terms on a future sale and purchase of livestock. These types of agreements and contracts are commonly referred to as AMAs. Pricing mechanisms vary across AMAs. Some AMAs rely on a reported spot, or negotiated, market price or exchange-based futures price for at least one aspect of its price, while others involve complicated pricing formulas with premiums and discounts based on carcass merits. The livestock producer and packer agree on a pricing mechanism under AMAs, but usually not on a specific price.

AMS reports the number of cattle sold to packers under formula, forward contract, and negotiated pricing mechanisms. Table 6 illustrates the prevalence of contracting in the marketing of fed cattle. Formula pricing methods and forward contracts are two forms of AMA contracts. Thus, the first two columns in the following table are cattle marketed under contract and the third column represents the spot market, or negotiated market, for fed cattle including negotiated grid. The data in the below table show that the AMA contracting of cattle has increased since 2010. Approximately 55 percent of fed cattle were marketed under contracts in 2010 (formula and forward contracts in the below table). By 2021, the percentage of fed cattle marketed to packers under AMA contracts had increased to just over 72 percent. These data also show the declines in the percentage of cattle sold on the spot market, or negotiated trades, from 46 in 2010 to 28 in 2021.

Table 6: Percentage of Fed Cattle Sold by Type of Purchase[260]

Year	Formula	Forward Contract	Negotiated
2010	44.9	9.5	45.6
2011	48.4	10.9	40.7
2012	54.7	11.4	33.8
2013	60.0	10.2	29.8
2014	58.1	14.2	27.6
2015	58.2	16.5	25.3
2016	58.2	12.0	29.8
2017	58.7	11.4	29.9
2018	62.0	8.8	29.2
2019	65.7	9.8	24.4
2020	64.1	9.0	27.0
2021	61.5	10.9	27.6

As previously discussed, and illustrated in Table 5 above, over 40 percent of hogs are grown under production contracts. These hogs are then sold by swine contractors to packers. The percentage of hogs sold under marketing contracts or produced by packers has increased to over 98 percent in 2020 (other marketing agreements and formula sales in the table below). The spot market, or negotiated trades, for hogs has declined from 5.2 percent in 2010 to 1.5 percent in 2020. As these data demonstrate, almost all hogs are marketed to packers under some type of marketing contract.

[259] Agricultural Census, 2012 and 2017, available at *https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf* (last accessed 8/9/2022).

[260] U.S. Department of Agriculture, Agricultural Marketing Service, available at: *https://mpr.datamart.ams.usda.gov/menu.do?path=Products\Cattle\Weekly%20Cattle* (last accessed Aug. 2022).

Table 7: Percentage of Hogs Sold by Type of Purchase[261]

Year	Other Marketing Arrangements[262]	Formula[263]	Negotiated
2010	45.4	49.4	5.2
2011	47.6	48.2	4.2
2012	47.7	48.6	3.6
2013	48.3	48.4	3.2
2014	45.9	51.4	2.7
2015	46.0	51.4	2.6
2016	50.0	47.6	2.5
2017	52.5	45.0	2.5
2018	56.5	41.3	2.2
2019	59.8	38.4	1.8
2020	61.3	37.1	1.5

The Need for the Rule: Structural Issues in the Cattle, Hog, and Poultry Industries

The livestock and poultry industries are characterized by a high volume of growing, production, and marketing contracts. When coupled with high levels of market concentration, this market environment can make it easier for regulated entities to engage in undue prejudice and unjust discrimination, retaliation, and deception and make the harms to producers greater from those abuses.

Despite various policy and public concerns, contracting, growing, production, and marketing contracts can offer certain benefits to the contracting parties. Properly tailored, benefits can include helping farmers, livestock producers, and processors manage price and production risks, elicit the production of products with specific quality attributes by tying prices to those attributes, and facilitate the smooth flow of commodities to processing plants. Such attributes may encourage certain efficiencies in use of farm and processing capacities. Quality-related attributes and standards can incentivize farmers to deliver products that consumers desire and produce products in ways that reduce processing costs.[264]

There are, however, trade-offs with the use of these contracts. In concentrated industries, like the cattle, hog, and poultry industries, where market power is present, these types of contracts may result in increased opportunities for undue prejudices and unjust discrimination, retaliation, and deception, among other concerns, which cause inefficiencies in the markets for livestock, poultry, and meat.[265] Heightened market concentration implies that livestock producers and poultry growers face fewer marketing and contract options compared to less concentrated markets. Livestock producers and poultry growers may find themselves in a take-it-or-leave it situation when a new or renewal contract is presented due to a limited number of packers and live poultry dealers with which to contract. Thus, livestock producers and poultry dealers entering into new, or renewal contracts may be taken advantage of through discriminatory, deceptive, or retaliatory practices.

Livestock and poultry contracts may lead to unjust, prejudicial, and retaliatory practices. For example, a contract that limits a poultry grower's services to a single integrator, even if the contract provides for fair compensation to the grower, still leaves the grower subject to risks. The grower faces the risk that the contractor may require additional capital investments or the contractor may impose lower returns at the time of contract renewal—leveraging its market power given the grower's limited options.[266] Some poultry make substantial long-term capital investments as part of livestock or poultry production contracts, including land, poultry or hog houses, and equipment. Those investments may bind the grower to a single contractor or integrator, furthering the indebtedness and exacerbating an imbalance of power.

In the poultry industry, limited integrator choice may accentuate contract risks. The data in Table 2 above show that 52 percent of broiler growers, who account for 56 percent of total production, report having only one or two integrators in their local areas. Even where multiple integrators are present, there are high costs to switching, owing to the differences in technical specifications that integrators require. The growers likely need to invest in new equipment and learn to apply different operational techniques due to different breeds, target weights, and grow-out cycles.

A 2006 survey indicated that growers with access to a single integrator received seven to eight percent less

[261] U.S. Department of Agriculture, Agricultural Marketing Service, available at: *https://mpr.datamart.ams.usda.gov/menu.do?path=\Products* (Last accessed Aug. 2022).

[262] Includes Packer Owned and Packer Sold, and Other Purchase Arrangements.

[263] Includes Swine Pork Market Formula, and Other Market Formula.

[264] RTI International, 2007, GIPSA Livestock and Meat Marketing Study, Prepared for USDA, GIPSA; Stephen R. Koontz, ''Another Look at Alternative Marketing Arrangement Use by the Cattle and Beef Industry,'' in Bart Fischer et al, ''The U.S. Beef Supply Chain: Issues and Challenges Proceedings of a Workshop on Cattle Markets,''.

[265] Nathan H. Miller, *et al.,* ''Buyer Power in the Beef Packing Industry: An Update on Research in Progress,'' April 13, 2022, available at *http://www.nathanhmiller.org/cattlemarkets.pdf.*

[266] *See* Vukina and Leegomonchai, ''Oligopsony Power, Asset Specificity, and Hold-Up: Evidence from The Broiler Industry,'' *American Journal of Agricultural Economics,* 88(3): 589–605 (August 2006).

compensation, on average, than farmers located in areas with four or more integrators.[267] If live poultry dealers already possess some market power to reduce prices for poultry growing services, some contracts can extend that power by raising the costs of entry for new competitors or allowing for price discrimination.[268]

In 2013, production contracts covered $58 billion in agricultural production, 83 percent of which was poultry and hog contracts.[269] Most hogs are produced and marketed under production and marketing contracts. Open market negotiated trade represented nine percent of total trades for hogs in 2008 and dropped to two percent in 2020.[270] In effect, the only production or marketing choice for a hog producer is to enter a contract.

In the cattle sector, cow-calf operations incur a significant investment in breeding stock and typically sell steers and heifers once a year. Access to competitive markets, absent from unjust discrimination, undue prejudice, and retaliation, is important to the economic livelihood of the market. Reduced marketing options—fewer options to sell on the spot market, or lack of access to contracts—can leave producers susceptible to unfair trade practices. Spot market trades, or negotiated trades, as opposed to marketing agreements or contracts, for fed cattle accounted for 51 percent of all trades in 2008 and fell to 29 percent in 2022.[271]

One indication of potential market power is industry concentration.[272] Market concentration facilitates the exclusionary and adverse treatment observed in discriminatory practices. The data in Table 1 are estimates of national four-firm concentration ratios at the national level, but the relevant economic markets for livestock and poultry may be regional or local, and concentration in the relevant market may be higher than the national level. For example, while poultry markets may appear to be the least concentrated in terms of the four-firm concentration ratios presented above, relevant economic markets for poultry growing services are more localized than markets for fed cattle or hogs, and local concentration in poultry markets is often greater than in hog and other livestock markets. The data presented earlier in Table 2 highlights this issue by showing the limited ability a poultry grower has to switch to a different integrator. As a result, national concentration may not demonstrate accurately the options poultry growers in a particular region face.

The levels of industry concentration shown in Tables 1 and 2 may contribute to oligopolistic market power and asymmetric information. The result is that the contracts bargained between the parties may leave livestock producers, swine production contract growers, and poultry growers vulnerable to anticompetitive conduct such as undue prejudice and unjust discrimination, retaliation, and deception.

The Need for the Rule: Asymmetric Information

There is asymmetry in the information available to livestock producers and livestock and poultry growers as compared to the packers, swine contractors, and live poultry dealers with whom they contract. The larger packers, swine contractors, and live poultry dealers generally have more information (costs of production, input quality, and consumer demand, for example) that is useful in contracting than the smaller livestock producers and livestock and poultry growers. This asymmetry of information can lead to deceptive practices by regulated entities with superior information in contract formation, performance, termination, or refusal by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading. A 2023 AMS rule, Transparency in Poultry Grower Contracting and Tournaments, directly aims to address this asymmetric information in the poultry industry by adding disclosures and information that live poultry dealers engaged in the production of broilers must furnish to poultry growers with whom dealers make poultry growing arrangements.[273] There remains a wide range of circumstances where information asymmetry is present in the livestock and poultry markets, which would be addressed in whole or in part by this final rule. Additionally, the information this rule provides can help producers know if they are treated unfairly.

Some marketing contracts for fed cattle, for example, use various plant averages in the calculation for the base price of the cattle in the marketing contract. Only the packer has the information about the plant averages and producers cannot independently verify the information. Similar issues exist in hog marketing contracts. For contracts based on the pork cutout, the hog packer has more information about the direct retail pork demand and hence pork cutout prices than hog sellers.

Live poultry dealers hold information on how individual poultry growers perform under a variety of contracts. The average number of contracts for the live poultry dealers filing annual reports with AMS in 2020 was 251. The largest live poultry dealers contracted with several thousand growers.[274]

Most growers producing poultry under production contracts are paid under a poultry grower ranking or ''tournament'' pay system. Under tournament systems, the contract between the poultry grower and the company for whom the grower raises poultry for slaughter pays the grower based on a grouping, ranking, or comparison of poultry growers delivering poultry to the same company during a specified period. Generally, live poultry dealers provide most of the inputs to all the growers in each poultry tournament used to determine grower pay. In these tournaments, the live poultry dealers have information about the quality of the inputs, while each grower only knows what he or she can observe. A grower may not be able to evaluate the inputs it received such as chicks and feed, and he or she almost certainly will not know about the inputs received by other growers. A live poultry dealer also has historical information concerning growers' production and income under many

[267] MacDonald, J. and N. Key. ''Market Power in Poultry Production Contracting? Evidence from a Farm Survey.'' *Journal of Agricultural and Applied Economics.* 44(4) (November 2012): 477–490.

[268] *See, e.g.,* Williamson, Oliver E. ''Markets and Hierarchies: Analysis and Antitrust Implications,'' *New York: The Free Press* (1975); Edlin, Aaron S. & Stefan Reichelstein (1996) ''Holdups, Standard Breach Remedies, and Optimal Investment,'' *The American Economic Review* 86(3): 478–501 (June 1996).

[269] MacDonald, J.M. ''Trends in Agricultural Contracts.'' Choices. 2015. Quarter 3. Available at *https://www.choicesmagazine.org/choices-magazine/theme-articles/current-issues-in-agricultural-contracts/trends-in-agricultural-contracts,* accessed 9–19–22.

[270] USDA, AMS, FTPP, Packers and Stockyards Division. Packer Annual Reports, 2021 and 2012. Available at *https://www.ams.usda.gov/reports/psd-annual-reports,* accessed 9–19–22.

[271] USDA, AMS, FTPP, Packers and Stockyards Division. Packer Annual Reports, 2021 and 2022 pending, and 2012. Available at *https://www.ams.usda.gov/reports/psd-annual-reports,* accessed 9–19–22.

[272] For additional discussion see MacDonald, J.M. 2016 ''Concentration, contracting, and competition policy in U.S. agribusiness,'' *Competition Law Review,* No. 1–2016: 3–8.

[273] Transparency in Poultry Grower Contracting and Tournaments. A Rule by the Agricultural Marketing Service on 11/28/2023. *https://www.federalregister.gov/documents/2023/11/28/2023-24922/transparency-in-poultry-grower-contracting-and-tournaments.*

[274] All live poultry dealers are required to annually file Packers and Stockyards Division (PSD) form 3002 ''Annual Report of Live Poultry Dealers,'' OMB control number 0581–0308. The annual report form is available to public on the internet at *https://www.ams.usda.gov/sites/default/files/media/PSP3002.pdf.*

different circumstances for all the growers with which the dealer contracts, while an individual grower, like most other producers, only has information concerning his or her own production and income. Prohibiting deception may serve to reduce the negative impacts from asymmetric information. Prohibiting retaliation against producers or growers because they joined a cooperative or grower association organization, shared information to improve their production or growing practices with a regulated entity, another covered producer, or with a commercial entity, communicated with the government, or asserted any of the rights granted under the Act should lead to reducing the information asymmetry between regulated entities and producers.

The Need for the Rule: Hold-Up Problem

Hold-up is another problem that is particularly acute in service contracts between poultry growers and live poultry dealers. The economic concept of a hold-up problem refers to a situation in which two parties may be unable to cooperate efficiently due to incomplete or asymmetric information and the inability to write, enforce, or commit to contracts. Once a party becomes locked into a transaction, especially as a result of making a transaction-specific investment, they become vulnerable to exploitation by the other party. This may involve one party to a contract opportunistically deviating from expectations of the other party or failing to live up to previously agreed upon terms.

In the poultry industry, hold-up occurs when a poultry grower makes an investment, such as in poultry housing, and becomes dependent upon the growing arrangement to repay the investment. Hold-up is less common for hog and cattle producers, so the discussion here is limited to poultry growing to highlight this risk to poultry growers. Substantial gaps exist between the periods of time covered by the contract and the mortgage on poultry housing, creating uncertainty around whether growers will be able to repay their debt and recoup their investments, introducing the potential for hold-up into the contracting process. If the integrator takes advantage of the grower's dependence, for example, by delaying delivery of chicks that the grower depends upon to make payments on investments, it would be holding up the grower. The aim of the economic hold-up may be to coerce the grower into accepting conditions that benefit the integrator at the expense of the grower. For example, refusing to supply chicks until a contract amendment with unfavorable conditions is signed.

This is of concern in poultry production contracts because the capital investment requirements related to growing chickens are significant and highly specialized (that is, they have little value outside of growing chickens). As a result, growers entering the market are tied to growing chickens to pay off the financing of the capital investment. Growers have reported that they must accept unfavorable contract terms or endure unfavorable treatment during a contract—including inappropriate limits on their ability to form associations, assert their rights under the law or contract (such as viewing the weighing of broilers), communicate with government entities, and seek alternative business relationships—because they are tied to production to pay off lenders and they have few, if any, alternative integrators with whom they can contract. Hog producers, which invest heavily in production facilities, may face similar risks.

Long term, this behavior may result in underinvestment in production, which is inefficient. Alternatively, if growers make a significant investment because they do not anticipate hold-up, but then it does occur, then growers may be required to spend too much on investments. The resulting over-investment in capital by those growers facing hold-up is also inefficient. The hold-up problem is a manifestation of both market power and asymmetric information.

Summary Need for the Rule: Contracting, Industry Structure, and Market Failure

As described previously, the organization and structure of poultry and livestock markets is characterized by regional market power; substantial investment in production capital that is specific to a single production purpose; and, in the poultry industry, nearly universal use of production contracts, and widespread use of marketing contracts in the cattle industry, while less so, for hogs. These conditions create the potential for market failures. Asymmetric information and imperfect competition are concerns in livestock and poultry markets. economically incomplete contracts and hold-up are of particular concern in poultry markets and can exacerbate the risk of undue prejudice and unjust discrimination, retaliation, and deception in poultry and livestock markets.

By setting forth specific prohibitions on unduly prejudicial and unjustly discriminatory and deceptive practices, the rule will reinforce producers' existing rights to gather and share information, while reducing the fear of retaliation and interference in the contracting process. The prohibitions in the rule will also continue to support, and possibly promote more efficient and equitable information access, reduce the hold-up problem, reduce retaliation, discourage false and misleading statements, and increase communication, cooperation, and retention of legal rights. The prohibitions specified in §§ 201.304 and 201.306 will ultimately assist in mitigating the impacts of imperfect competition.

Cost-Benefit Analysis of §§ 201.304 and 201.306

Regulatory Alternatives Considered

Executive Order 12866 requires an assessment of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulations and an explanation of why the planned regulatory action is preferable to the potential alternatives.[275] AMS considered three regulatory alternatives. The first alternative that AMS considered is to maintain the *status quo* and not propose §§ 201.304 and 201.306. The second alternative that AMS considered is to issue §§ 201.304 and 201.306 as presented in this rule.[276] This second alternative is AMS's preferred alternative as will be explained below. The third alternative that AMS considered is proposing §§ 201.304 and 201.306, but exempting small businesses, as defined by the Small Business Administration (SBA), from having to comply with the recordkeeping requirement of § 201.304(c).

Regulatory Alternative 1: Status Quo Alternative

If §§ 201.304 and 201.306 are never promulgated, there are no marginal costs and marginal benefits as industry participants will not alter their conduct. From a cost standpoint, this *Status Quo* Alternative is the least-cost alternative compared to the other two alternatives. This alternative also has no marginal benefits. Since there are no changes from the *status quo* under this

[275] *See* sec. 6(a)(3)(C), E.O. 12866.

[276] This final rule includes § 201.302, which defines a covered producer, livestock producer, and regulated entity. These definitions will apply to final §§ 201.304 and 201.306. The definitions final in § 201.302 are captured in the regulatory impacts of final §§ 201.304 and 201.306. The final rule also includes § 201.390 which states all provisions are severable in case any provision is declared invalid.

regulatory alternative, it will serve as the baseline against which to measure the other two alternatives.

Final Rule

As discussed above, final § 201.304 prohibits undue prejudice, unjust discrimination, and retaliation by regulated entities and adds a requirement for regulated entities to maintain records that they already keep, for up to a period of five years, related to its compliance with final § 201.304. Section 201.306 will prohibit deceptive practices by regulated entities in contract formation, performance, or termination by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading. Additionally, a regulated entity may not refuse a contract by providing false or misleading information to a covered producer or associations of covered producers.

Final Rule: Benefits

Reductions in prejudicial, discriminatory, retaliatory, and deceptive practices by packers, swine contractors, and live poultry dealers will benefit society. These types of conduct are inefficient, and often difficult to quantify for prejudicial, discriminatory, retaliatory, and deceptive practices are not necessarily written into contracts but in contract offers, preparation and enforcement. Production contracts need not change to realize benefits in this rule. The amount of benefits that depends on the extent to which the rule reduces prejudicial, discriminatory, retaliatory, and deceptive practices. That, in turn, is bounded by the degree to which any of these types of activities are occurring in the baseline. If the reductions are small, the benefits will be small. The greater the reductions, the greater the potential benefits. USDA's long-standing policy has been that the Act prohibits the type of conduct that final §§ 201.304 and 201.306 addresses.

Final §§ 201.304 and 201.306 add specificity to what constitutes undue prejudices, unjustly discriminatory practices, retaliation, and deception. The size of the benefits is difficult to quantify as it depends on the amount of undue prejudice, unjust discrimination and deception that will be avoided due to added specificity provided by the rule. The added benefits to the industry from final §§ 201.304 and 201.306 over the *Status Quo* occur when packers, swine contractors, and live poultry dealers alter their conduct to reduce instances of deceptive, prejudicial, and discriminatory practices, including retaliation. The potential benefits include protecting producer and grower rights, improved corporate culture, improved information, fewer deceptive practices, among others. The more undue prejudice, unjust discrimination, retaliation, and deception that will be avoided, the larger the benefits. AMS is unable to quantify the benefits and will present a qualitative discussion of the types of potential benefits that accrue from reductions in undue prejudice, unjust discrimination, retaliation, and deception.

Benefits: Protecting Producer and Grower Rights

A key purpose of specifying certain prohibitions on unduly prejudicial, discriminatory, and deceptive practices, including those in final §§ 201.304 and 201.306, is to protect livestock producers, swine contractors and poultry growers' rights under the Act. Final §§ 201.304 and 201.306 will also help protect producers from unfair and deceptive practices stemming from market power imbalances such as undue prejudice, unjust discrimination, retaliation, and deception by using false or misleading statements in contracting by packers and live poultry dealers. The benefits of prohibiting prejudicial, discriminatory, and deceptive practices, will accrue not only to the market's covered producers and cooperative producers who have been subjected to the prohibited practices, but also to those for whom the rule's deterrence effects will protect from future potential abuses.

Benefits: Addressing Imperfect Information

Several provisions in the final rule will enhance the protection of the rights of producers to lawfully communicate and to associate with others to explore business relationships and improve production practices and in the marketing of livestock, poultry, and meat. These provisions will benefit producers by encouraging the use of their currently existing legal rights that will solidify and enhance their access to information. This in turn will help address information asymmetry and thus help producers make better business decisions, enhance their competitiveness, reduce the hold-up problem, and promote innovation and economic efficiency in the industry.

The final rule will help close this information gap by protecting the rights of producers to form associations and communicate freely with one another, and to communicate with other regulated entities for the purpose of exploring a business relationship. This will benefit producers by improving their ability to strengthen the returns to their livestock and poultry investments, by enhancing the bargaining power of supplier groups if they elect to organize in such a way.

This rule will prohibit retaliation against covered producers due to their communicating, negotiating, or contracting with other covered producers, a commercial entity, consultant, or regulated entities, which could increase the important decision-making information available to producers. Improved safeguarding of protected activities may enable the producer to improve business decision-making and manage risk, including potentially acquiring external insurance and risk-management products. In addition, facilitating producers' ability to gain more and better information will help correct information asymmetry and improve transparency and completeness in contracts.

More information will also reduce the risks associated with hold-up as discussed above. By protecting rights to freely communicate and associate, this rule will facilitate communication across the industry that may help disseminate information regarding new innovations and best practices within the industry. These types of provisions that could provide producers with access to more and better information should promote innovation and economic efficiency in the industry.

The final rule may also serve to reduce the risk of violating sec. 202(a) of the Act because it will provide clarification to the livestock, and poultry industries as to the discriminatory and deceptive practices that will be prohibited under that section of the Act. Less risk through the clarification provided in the final rule will likely foster fairness in contracting by providing explicit protections for livestock producers, swine production contract growers, and poultry growers.

Benefits: Prohibiting Deceptive Practices

Final § 201.306 specifies prohibited practices that will be considered deceptive, and thus in violation of sec. 202(a) of the Act. Though USDA already protects producers from deceptive practices, the rule will explicitly protect suppliers from deception by packers and live poultry dealers by employing a false and misleading statement, or omission of material information necessary to make a statement not false or misleading in contracting. Prohibited deceptions, including false statements or omissions, can prevent or mislead producers, sellers, or buyers from making informed decisions and thus

represents a market inefficiency. The provisions in final §§ 201.304 and 201.306 will help give producers confidence that the information provided by processors is reliable, which will help them to make better and more informed business decisions and manage risk.

Other Benefits

While some of these protections already benefit individual producers, ensuring they cover the full marketplace and can be enforced individually adds to the integrity and fairness of livestock and poultry contracting. Specifying these protections may bring additional benefits above the *Status Quo* Alternative.

Production and marketing contracting has many benefits in the livestock and poultry industries. The final rule can further enhance the documented benefits of contracting by prohibiting unduly prejudicial, discriminatory, and deceptive practices. Livestock producers often have few choices of packers to which they sell, and poultry growers often have few choices in the live poultry dealers for which they raise poultry. The limited alternatives cause fear among producers that certain actions they might undertake, such as communication with government or other regulated entities to pursue business relationships, association with certain groups, or making lawful public complaints about the packers, swine contractors, or live poultry dealers might result in harmful retaliations. AMS intends the final rule to promote integrity to the marketplace by enhancing the protection of the rights of the producers and alleviating those fears.

The literature and data on these topics are not sufficient to allow AMS to estimate the magnitude of the inefficiencies that the final rule may correct above the *Status Quo* Alternative, nor the degree to which the additional producer and grower protections will address inefficiencies. Though AMS is unable to quantify the benefits of the regulation, this analysis has explained the types of benefits that will be derived from reductions in undue prejudice, unjust discrimination, retaliation, and deception. If the reductions are small, the benefits will be small. The greater the reductions, the greater the potential benefits.

Final Rule: Costs

The final rule will not impose any restrictions on numbers or types of production or marketing contracts that can be utilized, use of AMAs, poultry tournaments, or base price mechanisms in contracts for packers, swine contractors, and live poultry dealers. Instead, the final rule clarifies the prohibited unduly prejudicial, unjustly discriminatory, and deceptive practices that AMS considers violations of sections 202(a) and (b) of the Act. The final rule will require packers, live poultry dealers, and swine contractors to discontinue any prejudicial, unjustly discriminatory, or deceptive practices, if any are occurring. The practices prohibited by §§ 201.304 and 201.306 are the kind of practices that do not benefit society as a whole, but there is uncertainty about the extent of net costs to regulated entities of preventing them since they are based on behaviors and are not expressly written into contracts. In other words, §§ 201.304 and 201.306 result in uncertain-in-magnitude indirect costs resulting from adjustments by the livestock and poultry industries to reduce their use of AMAs, poultry tournaments, and pricing mechanisms, with the possibility of a number of changes to existing marketing or production contracts.

Though the magnitude of indirect costs is uncertain, AMS has constructed a scenario that indicates the magnitude is likely below an established dollar value benchmark. The following scenario illustrates why it is extremely unlikely that the rule's indirect costs will exceed the Unfunded Mandates Reform Act's (UMRA) cost compliance threshold of $170 million annually, a benchmark used to assess this rule's effects on the private sector.[277] If some cattle contracts are altered to come into compliance with the rule, and cattle prices to some producers are increased, AMS expects that the packers will offer, at most, the average price paid for cattle. Looking just at cattle, the weighted average difference between the minimum and average liveweight prices paid for cattle over the last nine years in four cattle regions reported by AMS Market News is $1.31 per cwt ($.01/lb.).[278] If AMS assumes that the entire difference between the minimum and average prices paid was due to unlawful discrimination, deception, and retaliation, this will require 13 billion pounds of liveweight cattle to meet the $170 million threshold.[279] This assumption does not account for any price differences for cattle related to quality of the animal. Taking the 2022 average liveweight per head for all cattle of 1,369 lbs. per head,[280] this means that 9.5 million head of cattle in one year would have to face conduct this rule aims to prohibit to equal $170 million in costs in that year.[281] This number accounts for 28 percent of all cattle slaughtered in 2022.[282] Based on AMS's knowledge of the livestock industry, it is not expected that the number of cattle affected by unlawful discrimination, retaliation, or deception reaches this level. This fact, combined with the unrealistic assumption that any price deduction below the average price does not account for quality differences and is wholly the result of discrimination, retaliation, and deception, points to a conclusion that this rule will have limited impacts, and not exceed the UMRA threshold.

Litigation Costs

AMS expects §§ 201.304 and 201.306 to reduce litigation costs due to increased compliance with the rule associated with the clarity provided by the rule as to the conduct that violates the Act, but also to increase litigation as this rule allows producers to find relief in courts. AMS is uncertain as to which of these offsetting effects will dominate and to what extent. The final rule clarifies the prohibited unduly prejudicial, discriminatory, and deceptive practices that will violate section 202(a) of the Act. The clarification could result in a reduction in litigation costs if companies come

[277] Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal Governments and on the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures of $100 million or more (adjusted for inflation) in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. Congressional Research Service. Updated February 23, 2021. Unfunded Mandates Reform Act: History, Impact, and Issues. Accessed at *https://crsreports.congress.gov/product/pdf/R/R40957/109* on 02/08/2024.

[278] Data for negotiated steers and heifers, across all Choice cattle, four cattle regions, 2015–2023. Sources: U.S. Department of Agriculture, Agricultural Marketing Service. Texas-Oklahoma-New Mexico Weekly Direct Slaughter Cattle—Negotiated Purchases (LM_CT156), Kansas Weekly Direct Slaughter Cattle—Negotiated Purchases (LM_CT157), Nebraska Weekly Direct Slaughter cattle—Negotiated Purchases (LM_CT158), and Iowa/Minnesota Weekly Weighted Average Cattle Report—Negotiated (LM_CT167).

[279] 13 billion lbs. = UMRA $170 million threshold divided by $0.01 per lb. (difference between the minimum and average liveweight prices paid for cattle over the last nine years in eight cattle markets is $1.31 per cwt ($.01/lb.)).

[280] U.S. Department of Agriculture, National Agricultural Statistical Service. April 2023. Livestock Slaughter 2022 Summary. Accessed at *https://downloads.usda.library.cornell.edu/usda-esmis/files/r207tp32d/8p58qs65g/g445dv089/lsan0423.pdf* on 02/08/2024.

[281] 9.5 million head of cattle = 13 million lbs. of cattle divided by 1,369 lbs. per head.

[282] 28 percent = (9,479,254 head divided by 34,300,00 head annual slaughter) multiplied by 100.

into compliance without any enforcement action. These regulations encourage regulated entities to proactively avoid prejudicial, discriminatory, and deceptive practices that could otherwise lead to costly litigation. Further, some firms may develop policies and procedures to comply with the recordkeeping requirements. This effect could reduce litigation and thus result in reduced litigation costs for regulated entities.

However, there are several provisions in § 201.304 that could result in additional litigation. AMS has received formal and informal complaints against packers, swine contractors, and live poultry dealers for retaliation for belonging to various producer and grower associations, contacting AMS to file a complaint, asserting legal rights, and contacting a competing regulated entity to pursue a contractual relationship. Similarly, there are several provisions in § 201.306 that could result in additional litigation, including refusals by regulated entities to enter into or renegotiate contracts and contract terminations by producers. The clarity of the practices that AMS considers to be discriminatory and deceptive in §§ 201.304 and 201.306 could offer producers new hope for relief from courts for undue prejudicial, discriminatory, and deceptive practices by regulated entities. This effect could result in increased litigation.

As stated above, AMS is uncertain as to which effect will dominate and to what extent. AMS does not estimate litigation costs in this analysis.

Direct Costs of the Final Rule

AMS expects §§ 201.304 and 201.306 will result in direct administrative and recordkeeping costs to the industry. AMS expects that packers, swine contractors, and live poultry dealers will incur direct administrative costs of learning the rule and then reviewing and, if necessary, revising marketing and production contracts to ensure compliance with §§ 201.304 and 201.306. Regulated entities will also incur recordkeeping costs from keeping the records they already maintain for up to five years as required under § 201.304. The expected total costs of §§ 201.304 and 201.306 will be the direct administrative costs and recordkeeping costs of that regulatory alternative. The direct administrative costs and recordkeeping costs will be estimated below.

Direct Administrative Costs of the Final Rule

AMS expects that §§ 201.304 and 201.306 will prompt packers, live poultry dealers, and swine contractors to first review and learn the rule and then review their procurement policies and production contracts and make any necessary changes to ensure compliance with the new regulations. Expected costs are estimated as the total value of the time required to review and learn the rule and then review and, if necessary, revise procurement and production contracts.

AMS expects the direct administrative costs of complying with §§ 201.304 and 201.306 will be relatively small.

The certain types of benefits outlined above will be in proportion to the extent to which the rule reduces prejudicial, discriminatory, retaliatory, and deceptive practices. The USDA policy has long held that several of the provisions in §§ 201.304 and 201.306 or similar provisions were violations of the Act, although the position has not been established in regulations. Consequently, AMS expects packers, live poultry dealers, and swine contractors to make changes to relatively few contracts.

The direct costs of the rule are low because the discriminatory, retaliatory, and deceptive behavior which the rule seeks to mitigate are not overtly written into the terms of the contracts between regulated entities and producers. They are behaviors or conduct in which some regulated entities engage, for example by not offering contracts to some producers due to discrimination and retaliation or by offering less favorable contract terms due to discrimination, retaliation, and deception. If the rule results in less discriminatory, retaliatory, or deceptive behavior by regulated entities, the costs of offering a contract to a producer or grower that was previously denied a contract or amending the terms of a less favorable contract to an impacted producer or grower will be of uncertain. Given that the behavior that the rule seeks to mitigate is not overtly written into contracts and is behavior during the contract offering process, the potential costs of mitigating the behavior are uncertain. The more that discriminatory, retaliatory, and deceptive behavior is mitigated because of the rule, the greater the benefits. AMS does not expect any changes in types of production and marketing contracts offered. AMS expects the same types of contracts to be offered, but with more equitable performance under the contracts by regulated entities across producers, fewer producers denied or terminated from contracts, and better clarity regarding contractual expectations. AMS also expects more contracts to be offered to producers who may not previously have been offered a contract due to discrimination, for example. Given its professional expertise based on regulating the industry and investigating complaints of the prohibited behaviors, AMS does not believe that the discriminatory, retaliatory, and deceptive behavior addressed by this rule is written into contract terms frequently enough to warrant changes to very many contracts.

Although the amount of indirect costs is uncertain, AMS expects any indirect costs will likely range from marginal to modest. As shown above, AMS acknowledges that some regulated entities may offer higher prices to some livestock producers and growers when they come into compliance with this rule. This could shift livestock and poultry prices offered to some producers and growers toward the true value of their livestock or poultry that would prevail in a more competitive market and away from the artificially low prices offered through the abuse of market power by engaging in deception, discrimination, or retaliation. This would reduce the cost to society due to the market inefficiency (dead weight loss) created by discriminatory, retaliatory, and deceptive practices by some regulated entities. This shift in prices offered to some producers and growers toward their true value would result, in some instances, in a transfer of excess profits (profits that exceed those that would be earned in a more competitive market) from regulated entities to some growers and producers. This transfer from regulated entities to some producers and growers could occur. AMS cannot quantify the extent to which the behavior this rule aims to prohibit occurs in the industry or the extent of any harm that would be avoided by regulated entities' cessation of the behavior under the clearer limitations set by this rule. AMS notes that regulated entities, in their comments to the proposed rule, asserted that the occurrence of the practices addressed in the rule are not widespread. Assuming this is true, the indirect costs will be marginal. AMS, however, has noted the behaviors have been sufficiently widespread to warrant the intervention provided by this final rule.

Estimates of the amount of time required to review and learn the rule and to review and revise contracts and keep records were provided by AMS subject matter experts. These experts were auditors and supervisors with many years of experience in AMS's PSD conducting investigations and compliance reviews of regulated entities. In May 2022, BLS released

Occupational Employment and Wage Statistics that AMS used for the time values in this analysis.[283] BLS estimated an average hourly wage for general and operations managers in animal slaughtering and processing to be $61.24. The average hourly wage for lawyers in food manufacturing was $103.81. In applying the cost estimates, AMS marked up the wages by 41.79 percent to account for fringe benefits.[284]

AMS expects that each packer, swine contractor, and live poultry dealer will spend one hour of legal time and one hour of management time to review and learn the rule and then, if necessary, revise production and marketing contracts to ensure compliance with the rule.

Live poultry dealers are currently required to file form PSD 3002, ''Annual Report of Live Poultry Dealers,'' OMB control number 0581–0308, with AMS. Ninety live poultry dealers filed annual reports with AMS for their 2021 fiscal year.

Packers are currently required to file form PSD 3004, ''Annual Report of Packers'' OMB control number 0581–0308, with AMS. Among other things, each packer reports the number of head of cattle or calves, hogs, and lamb, sheep, or goats that it processed. Three hundred sixty-five packers that processed cattle or calves, hogs, or lamb, sheep or goats filed reports or were due to file a report with AMS for their fiscal year 2021. Two hundred sixty-one were beef or veal packers. One hundred ninety-six were pork packers, and 139 were lamb, sheep, or goat packers.[285] The number of beef, pork, and lamb packers do not sum to 365 because many firms slaughtered more than one species of livestock. For instance, 112 packers slaughtered both beef and pork, and 66 slaughtered beef, pork, and lamb.

AMS expects that packers processing more than one species of livestock will not incur additional costs for each species. That is, AMS expects that each packer will require one hour of attorney's time and one hour of management time regardless of how many species of livestock it processes. To allocate costs across (1) beef, (2) pork, and (3) lamb processors, AMS allocated one-third of the costs to each of (1) beef, (2) pork, and (3) lamb for packers that processed all three species. For packers processing any two, AMS allocated one half the costs to each.

AMS estimated that all live poultry dealers that are regulated under the final rule will require one hour of an attorney's time costing the industry $13,000 [286] and one hour of management time costing the industry $8,000 [287] for learning the rule, reviewing, and adjusting contracts. The total costs for learning, reviewing, and adjusting contracts will be $21,000 [288] for live poultry dealers.

AMS expects that packers will require an estimated one hour of an attorney's time and one hour of management time costing the industry $85,000. AMS estimates the total costs will be $40,000 for beef packers and $16,000 for lamb packers to learn and review the rule and adjust contracts.[289] Pork packers' share of the packers' costs will be $29,000. AMS also expects that rule will cost all 575 swine contractors an hour of an attorney's time and one hour of management time costing a total of $135,000 across all swine contractors.[290] Combining costs to pork packers with costs to swine contractors arrives at a total cost of $164,000 for hog and pork markets.

Direct Recordkeeping Costs for the Final Rule

Costs to comply with the recordkeeping requirements are likely relatively low. Section 201.304(c) requires specific records that, if the regulated entity maintains, should be kept for a period of five years, including policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, board of directors' oversight materials, and any records of the number and nature of unduly prejudicial or unjustly discriminatory-based complaints received.

Costs of recordkeeping include regulated entities maintaining and updating compliance records and are considered a direct cost. Some smaller regulated entities that currently don't maintain records may voluntarily decide to develop formal policies, procedures, training, etc. to comply with the rule and will then have records to maintain.

AMS expects the recordkeeping costs will comprise the time required by regulated entities to store and maintain records they already keep. AMS expects that the costs will be relatively small because many packers, live poultry dealers, and swine contractors may currently have few records concerning policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, and board of directors' oversight materials related to prejudicial treatment. Some smaller firms might not have any records to store. Others already store the records and may have no new costs.

AMS estimated that recordkeeping time for larger entities will be greater than for smaller entities, and thus estimated costs by quartiles, from largest entities to smallest. AMS estimated that § 201.304(c) will require packers, live poultry dealers, and swine contractors in each quartile an average 4.00 hours, 2.00 hours, 1.33 hours, and 0.67 hours of administrative time for the first, second, third, and fourth quartiles, respectively. Additionally, AMS estimated that the hours required of managers, attorneys, and information technology staff each will average 1.50 hours, 0.75 hours, 0.50 hours, and 0.25 hours for the first, second, third, and fourth quartiles, respectively.

AMS also expects that packers, live poultry dealers, and swine contractors will incur continuing recordkeeping costs in each successive year. AMS estimated that § 201.304(c) will require an average of 3.00 hours, 1.50 hours, 1.00 hour, and 0.50 hour of administrative assistant time; 1.50 hours, 0.75 hour, 0.50 hour, and 0.25 hour of time each from managers and attorneys; and 1.00 hour, 0.50 hour, 0.33 hour, and 0.17 hour of time from information technology staff for packers, live poultry dealers, and swine contractors in the first, second, third, and fourth quartiles, respectively, to setup and maintain the required records in each succeeding year.

Estimated first-year costs for recordkeeping requirements in § 201.304(c) totaled $30,000 for live poultry dealers,[291] $193,000 for swine

[283] Estimates are available at U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics, available *https://www.bls.gov/oes/special-requests/oesm22all.zip* (accessed 7/14/2023).

[284] Estimates are available at U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics, available *https://www.bls.gov/oes/special-requests/oesm22all.zip* (accessed 7/14/2023).

[285] For brevity, all beef and veal packers will be collectively referred to as beef packers and all lamb, sheep, and goat packers will be collectively referred to as lamb packers.

[286] 90 live poultry dealers × $147.19 per hour × 1 hour = $13,247.

[287] 90 live poultry dealers × $86.83 per hour × 1 hour = $7,815.

[288] $13,247 + $7,815 = $21,062.

[289] 365 × ($147.19 per hour × 1 hour + $86.83 per hour × 1 hour) = $85,417.

[290] 575 × ($147.19 per hour × 1 hour + $86.83 per hour × 1 hour) = $134,562.

[291] 90 live poultry dealers × (($44.51 per hour admin. Cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost

Continued

contractors,[292] and $122,000 for packers.[293] Estimated yearly continuing costs for recordkeeping requirements in § 201.304(c) totaled $26,000 for live poultry dealers,[294] $166,000 for swine contractors,[295] and $106,000 for packers.[296]

Breaking out costs by market, AMS expects recordkeeping requirements in § 201.304(c) to cost beef packers $58,000 in the first year and $50,000 in each following year. Section 201.304(c) will cost lamb packers $23,000 in the first year and $20,000 in successive years. Section 201.304(c) will cost pork packers $42,000, and it will cost swine contractors $193,000 for a total of $235,000 in the first year. Section 201.304(c) will cost swine contractors $166,000 in successive years, and it will cost pork packers $36,000 for a total $202,000.

Total Direct Administrative & Recordkeeping Costs for the Final Rule

Table 8 below summarizes combined expected administrative and recordkeeping costs for regulated entities in the first year and in succeeding years. AMS expects that administrative and recordkeeping costs associated with §§ 201.304 and 201.306 will cost each packer, swine contractor, and live poultry dealer an average $569 in the first year and an average $289 in each succeeding year. First-year costs will total $51,000 for live poultry dealers, $327,000 for swine contractors, and $208,000 for packers. Costs in successive years will be due to recordkeeping requirements and will total $26,000 for live poultry dealers, $166,000 for swine contractors, and $105,000 for packers annually.

Table 8: Expected First-Year Cost and Succeeding Years Costs for Live Poultry Dealers, Packers, and Swine Contractors

	First-Year Cost ($)	Cost for Each Succeeding Year ($)
Average Cost per Live Poultry Dealer	569	289
Average Cost per to Swine Contractor	569	289
Average Cost per Packer	569	289
Total Cost to Live Poultry Dealers	51,000	26,000
Total Cost to Swine Contractors	327,000	166,000
Total Cost to Packers	208,000	105,000**
Beef Packers*	98,000	50,000
Pork Packers*	71,000	35,000
Lamb Packers*	39,000	20,000
Total Cost	586,000	298,000

*Many packers process more than one species of livestock, but AMS expects that each packer will require one hour of attorney's time and one hour of management time regardless of how many species of livestock it processes. To allocate costs across 1) beef, 2) pork, and 3) lamb processors, AMS allocated one-third of the costs to each of 1) beef, 2) pork, and 3) lamb for packers that processed all three species.

**Column total may not sum due to rounding.

× (1.5 hours + .75 hours + .5 hours + .25 hours)))/4 = $30,132.

[292] 575 swine contractors × (($44.51 per hour admin. cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost × (1.5 hours + .75 hours + .5 hours + .25 hours)))/4 = $192,507.

[293] 365 packers × (($44.51 per hour admin. cost × (4 hours + 2 hours + 1.33 hours + .67 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($93.68 information tech cost × (1.5 hours + .75 hours + .5 hours + .25 hours)))/4 = $122,200.

[294] 90 live poultry dealers × (($44.51 per hour admin. cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours)))/4 = $26,021.

[295] 575 swine contractors × (($44.51 per hour admin. Cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours)))/4 = $166,244.

[296] 365 packers × (($44.51 per hour admin. cost × (3 hours + 1.5 hours + 1 hours + .5 hours)) + ($86.83 per hour manger cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + ($147.19 legal cost × (1.5 hours + .75 hours + .5 hours + .25 hours)) + $93.68 information tech cost × (1 hours + .5 hours + .33 hours + .17 hours)))/4 = $105,529.

The total direct administrative and recordkeeping costs are estimated to be $586,000 in the first year. Estimated first year total direct administrative and recordkeeping costs for the cattle and beef industry, hogs and pork, lamb, and poultry industries rounded to the nearest thousand dollars are listed in the following table.

Table 9: Direct Administrative and Recordkeeping Costs for §§ 201.304 and 201.306 in 2023

Cattle ($ Th)	Hogs ($ Th)	Lambs ($ Th)	Poultry ($ Th)	Total ($ Th)
98	398	39	51	586

Final Rule: Ten-Year Total Direct Administrative and Recordkeeping Costs

Expected administrative and recordkeeping costs of §§ 201.304 and 201.306 for each year from 2023 through 2032 appear in the table below. Based on the analysis, AMS expects the ten-year total direct administrative and recordkeeping costs of §§ 201.304 and 201.306 to be $3.3 million.

Table 10: Ten-Year Total Direct Administrative and Recordkeeping Costs of §§ 201.304 and 201.306*

Year	Cattle ($ Th)	Hogs ($ Th)	Lambs ($ Th)	Poultry ($ Th)	Total ($ Th)
2023	98	398	39	51	586
2024	50	202	20	26	298
2025	50	202	20	26	298
2026	50	202	20	26	298
2027	50	202	20	26	298
2028	50	202	20	26	298
2029	50	202	20	26	298
2030	50	202	20	26	298
2031	50	202	20	26	298
2032	50	202	20	26	298
Totals	**547**	**2,216**	**217**	**285**	**3,266**

*Column total may not sum due to rounding.

Final Rule: Present Value of Ten-Year Total Direct Administrative and Recordkeeping Costs

Costs to be incurred in the future are lower than the same costs to be incurred today. This is because the money that will be used to pay the costs in the future can be invested today and earn a return on investment until the period in which the cost is incurred. After the cost has been incurred, the earned returns will still be available.

To account for the time value of money, the administrative costs to be incurred in the future are discounted back to today's dollars using a discount rate. The sum of all costs discounted back to the present is called the present value (PV) of total costs. AMS relied on both a three percent and seven percent discount rate as discussed in Circular A–4.[297]

[297] Circular A–4. September 17, 2003, available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*. Note: OMB issued an updated Circular A–4 on November 9, 2023. AMS developed its analysis for this final rule using the 2003 Circular A–4 guidance. The 2023 guidance is effective March 1, 2024, and applies to draft final rules submitted to OMB's Office of Information and Regulatory Affairs after December 31, 2024. The 2023 guidance is available at *https://*

Continued

AMS calculated the PV of the ten-year total direct administrative and recordkeeping costs of the regulations using a three percent and seven percent discount rate. The PVs appear in Table 11.

Table 11: PV of Ten-Year Direct Administrative and Recordkeeping Cost of §§ 201.304 and 201.306

Discount Rate	Final Rule ($ Th)
Three Percent	2,820
Seven Percent	2,361

AMS expects the PV of the ten-year total administrative and recordkeeping costs of §§ 201.304 and 201.306 to be $2.8 million at a three percent discount rate and $2.4 million at a seven percent discount rate.

Final Rule: Annualized PV of Ten-Year Total Direct Administrative and Recordkeeping Costs

AMS then annualized the PV of the ten-year total administrative and recordkeeping costs (referred to as annualized costs) of §§ 201.304 and 201.306 using both a three percent and seven percent discount rate as required by Circular A–4 and the results appear in Table 12.[298]

Table 12: Annualized Direct Administrative and Recordkeeping Costs of §§ 201.304 and 201.306

Discount Rate	Final Rule ($ Th)
Three Percent	331
Seven Percent	336

AMS expects the annualized ten-year administrative and recordkeeping costs of final §§ 201.304 and 201.306 to be $331,000 at a three percent discount rate and $336,000 at a seven percent discount rate.

Cost-Benefit Comparison of the Final Rule

The expected costs of this rule are very small relative to the size of the industry; and expected benefits are expected to be proportional to reductions in conduct this rule addresses. Combined sales of beef, pork, and broiler chicken in the U.S. for 2022 were approximately $294.5 billion.[299] As discussed above, the total cost of §§ 201.304 and 201.306 in the first year is estimated to be $586,000, or 0.0002 percent of revenues. A reduction in prejudicial, discriminatory, retaliatory, and deceptive practices will lead to benefits that will be directly related to the reductions in these practices. If the reductions are small, the benefits will be small. The greater the reductions, the greater the benefits. AMS expects that the costs and benefits to society from the rule will be very small in relation to the total value of industry production, leading to negligible indirect effects on industry supply and demand, including price and quantity effects.

Regulatory Alternative 3: Small Business Exemption Alternative

The third regulatory alternative that AMS considered is issuing §§ 201.304 and 201.306, but exempting small businesses, as defined by the SBA, from compliance with the recordkeeping requirement of § 201.304(c).[300] All other provisions of §§ 201.304 and 201.306 will still apply to small businesses. Most packers are small businesses under the SBA definition. Of the 365 packers reporting to AMS, 348 are small businesses. Two hundred fifty-three beef packers and 183 pork packers are small businesses. All 139 lamb packers are small businesses. Packers include multi-species packers. One hundred eight swine contractors are small businesses. There are 55 small poultry dealers.

Regulatory Alternative 3: Total Costs of the Small Business Exemption Alternative

Table 13 summarizes combined expected administrative and recordkeeping costs for regulated entities in the first year and in succeeding years. AMS expects that administrative and recordkeeping costs associated with a small business exemption alternative will cost each live poultry dealer, swine contractor, and packer an average of $448, $548, and $265, respectively, in the first year. AMS expects costs to average $185, $271, and $27 for live poultry dealers, swine contractors, and packers, respectively, in each succeeding year. First-year costs will total $40,000 for live poultry dealers, $315,000 for swine contractors, and $97,000 for packers.

www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.

[298] Circular A–4. September 17, 2003, available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.*

[299] Total meat and poultry processing industry revenues. Source: *https://www.ibisworld.com/industry-statistics/market-size/meat-beef-poultry-processing-united-states/#:~:text=The%20market%20size%2C%20measured%20by,industry%20increased%200.2%25%20in%202022.*

[300] *See,* ''Stay legally compliant (*sba.gov*),'' *available at https://www.sba.gov/business-guide/manage-your-business/stay-legally-compliant* (Last accessed 8/9/2022).

Costs in successive years will be due to recordkeeping requirements and will total $17,000 for live poultry dealers, $156,000 for swine contractors, and $10,000 for packers annually. The total direct administrative and recordkeeping costs are estimated to be $452,000 in the first year.

Table 13: Small Business Recordkeeping Exemption Alternative Expected First-Year Cost and Succeeding Years Costs for Live Poultry Dealers, Packers, and Swine Contractors

	First Year Cost ($)	Cost for Each Succeeding Year ($)
Average Cost per Live Poultry Dealer	448	185
Average Cost per Swine Contractor	548	271
Average Cost per Packer	265	27
Total Cost to Live Poultry Dealers	40,000	17,000
Total Cost to Swine Contractors	315,000	156,000
Total Cost to Packers	97,000	10,000
Beef Packers*	44,000	3,000
Pork Packers*	36,000	6,000
Lamb Packers*	16,000	0
Total Cost	452,000	183,000

*Many packers process more than one species of livestock, but AMS expects that each packer will require one hour of attorney's time and one hour of management time regardless of how many species of livestock it processes. To allocate costs across 1) beef, 2) pork, and 3) lamb processors, AMS allocated one-third of the costs to each of 1) beef, 2) pork, and 3) lamb for packers that processed all three species.

As discussed above, AMS considers the total costs from §§ 201.304 and 201.306 to be increased direct administrative and recordkeeping costs with no indirect costs from adjustments by the cattle, hog, and poultry industries to reduce their use of AMAs, change to pricing mechanisms or poultry tournaments, and no substantial changes to existing marketing, or growing or production contracts. AMS estimated the costs to small business from the direct administrative costs of §§ 201.304 and 201.306 but excluded the recordkeeping costs of § 201.304(c) in this alternative option.

AMS estimated the costs to small business to be the value of the time for management, attorneys, administrative staff, and information technology staff to review the rule and the firms' practices determining compliance with the direct administrative costs of §§ 201.304 and 201.306. AMS estimated costs for the Small Business Exemption Alternative similarly to the final rule. The only difference is the recordkeeping costs of § 201.304(c) attributable to small business are not included in the costs for the Small Business Exemption Alternative. The estimates appear in Table 14. Costs for the final rule are also shown for convenience.

Table 14: Annual Total Direct Costs: Small Business Exemption Alternative

Year	Final Rule ($ Th)	Small Business Exemption Alternative ($ Th)
2023	586	427
2024	298	182
2025	298	182
2026	298	182
2027	298	182
2028	298	182
2029	298	182
2030	298	182
2031	298	182
2032	298	182
Total	**3,266**	**2,067**

AMS estimates that §§ 201.304 and 201.306, with the small business exemption, will result in $427,000 in direct total costs in the cattle, hog, lamb, and poultry industries in the first full year following implementation and $182,000 each year in ongoing costs. AMS expects the ten-year total costs of § 201.304 and 201.306 with a small business exemption to be $2.1 million. Exempting small business will save approximately $159,000 in the first year and $1.1 million over ten years.

Regulatory Alternative 3: PV of Total Costs of the Small Business Exemption Alternative

AMS calculated the PV of the ten-year total costs of the Small Business Exemption Alternative using both a three percent and seven percent discount rate and the PVs appear in the following table. Costs for the final rule are also shown for convenience.

Table 15: PV of Ten-Year Total Cost: Small Business Exemption

Discount Rate	Final Rule ($ Th)	Small Business Exemption Alternative ($ Th)
Three Percent	2,820	1,792
Seven Percent	2,361	1,509

AMS expects the PV of the ten-year total costs of §§ 201.304 and 201.306 with a small business exemption to be $1.8 million at a three percent discount rate and $1.5 million at a seven percent discount rate.

Regulatory Alternative 3: Annualized Costs of the Small Business Exemption Alternative

AMS then annualized the PV of the ten-year total costs of §§ 201.304 and 201.306 with a small business exemption using both a three percent and seven percent discount rate and the results appear in Table 16. The final rule is also shown for convenience.

Table 16: Ten-Year Annualized Costs - Small Business Exemption

Discount Rate	Final Rule ($ Th)	Small Business Exemption Alternative ($ Th)
Three Percent	331	210
Seven Percent	336	215

AMS expects the annualized costs of §§ 201.304 and 201.306 with a small business exemption to be $210,000 at a three percent discount rate and $215,000 at a seven percent discount rate.

Cost-Benefit Comparison of Regulatory Alternatives

The status quo alternative has zero marginal costs. AMS compared the annualized costs of the final rule to the annualized costs of the Small Business Exemption Alternative by subtracting the annualized costs of the Small Business Exemption Alternative from those of the final rule and the results appear in Table 17.

Table 17: Difference in Ten-Year Annualized Costs of §§ 201.304 and 201.306 Between the Final Rule and Small Business Exemption Alternative

Discount Rate	($ Th)
Three Percent	121
Seven Percent	121

The annualized costs of the Small Business Exemption Alternative are $121,000 less expensive using a three percent discount rate and $121,000 less expensive using a seven percent discount rate. As is the case with costs, the benefits will be highest for the final rule because the full benefits will be received by all livestock producers and poultry growers, not just those doing business with large packers, swine contractors and live poultry dealers.

Though the Small Business Exemption Alternative will save approximately $121,000 on an annualized basis, AMS chose final §§ 201.304 and 201.306 over the Small Business Exemption Alternative because AMS wishes to prevent broadly the kind of undue prejudices and unjust discrimination described in the rule. AMS believes that keeping relevant records will help promote compliance with this rule, that all packers, live poultry dealers, and swine contractors cannot purchase livestock or enter into contracts for growing services with the kind of undue prejudices and unjust discrimination described in the rule.

AMS considered all three regulatory alternatives and believes that the final rule is the best alternative, as it benefits all livestock producers, swine production contract growers, and poultry growers, regardless of the size of the packer, swine contractor, or live poultry dealer with which they contract above the *Status Quo* Alternative.

Regulatory Flexibility Analysis

As part of the regulatory process, a Regulatory Flexibility Analysis (RFA) is conducted in order to evaluate the effects of this rule on small businesses. Under the final rule, there are no new regulatory text changes that would change the proposed rule costs and benefits of the regulatory analyses.

The SBA defines small businesses by their North American Industry Classification System Codes (NAICS).[301] Live poultry dealers, NAICS 311615, are considered small businesses if they have fewer than 1,250 employees. Meat packers, including, beef, veal, pork, lamb, and goat packers, NAICS 311611, are small businesses if they have fewer than 1,000 employees. Swine contractors, NAICS 112210, are considered small if their sales are less than $1 million annually.

AMS maintains data on live poultry dealers from the annual reports these firms file with AMS. Currently, 90 live poultry dealers will be subject to the regulation. Fifty-five of the live poultry dealers will be small businesses according to the SBA standard.

AMS records identified 365 packers that file annual reports or are due to file with PSD for their 2021 fiscal year. Two hundred sixty-one were beef packers. One hundred ninety-six were pork packers, and 139 were lamb or goat packers. Many firms slaughtered more than one species of livestock. For instance, 112 packers slaughtered both beef and pork.

Most packers will be small businesses, although large packers are responsible for most meat production. Three hundred forty-eight packers will be small businesses. Two hundred fifty-three beef packers and 183 pork packers were small businesses. All 139 lamb and goat packers were small businesses.

AMS does not have similar records for swine contractors because they are not required to register with AMS or provide annual reports. Table 24 of the 2017 USDA Census of Agriculture indicated that there were 575 swine contractors in 2017. The Census of Agriculture table has categories for the number of head that swine contractors sold, but not the value of the head sold. AMS expects that the 467 swine contractors that sold 5,000 head of hogs or more were large businesses, and the 108 contractors that sold less than 5,000 head were small businesses.

AMS estimated the costs in two parts. First, AMS expects that each packer, swine contractor, and live poultry dealer will review and learn the new rule and, if necessary, revise production and marketing contracts to ensure compliance with the new rule. Second, AMS expects that packers, live poultry dealers, and swine contractors will have additional costs associated with the new recordkeeping requirements in § 201.304(c).

AMS estimated that costs for reviewing and learning the final rule to small live poultry dealers, small packers, and small swine contractors will consist of one hour of a manager's time and one hour of a lawyer's time to review the requirements of §§ 201.304 and 201.306. Expected first-year costs will be $234 [302] for each live poultry dealer, each swine contractor, and each packer. This will amount to a total $13,000 for the 55 live poultry dealers, $81,000 for the 348 packers, and $25,000 for the 108 swine contractors.

Concerning the recordkeeping requirements in final § 201.304(c), AMS expects the cost will be comprised of the time required to store and maintain records already kept. AMS expects that the costs will be relatively small

[301] U.S. Small Business Administration. *Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Effective August 19, 2019.* ''The SBA Issues a Final Rule to Adopt NAICS 2017 for Small Business Size (last accessed 8/9/2022).'' Available at *https://www.sba.gov/article/2018/feb/27/sba-issues-final-rule-adopt-naics-2017-small-business-size-standards.*

[302] $147.19 per hour × 1 hour of an attorney's time + $86.83 per hour × 1 hour of a manager's time = $234.

because packers, live poultry dealers, and swine contractors will likely have few records concerning policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, and board of directors' oversight materials related to prejudicial treatment. Many firms might not have any records to maintain. Others already maintain the records and have no new costs.

AMS expects that recordkeeping costs will be correlated with the size of the firms. AMS ranked packers, live poultry dealers, and swine contractors by size and grouped them into quartiles, estimating more recordkeeping time for larger entities than for the smaller entities. AMS estimated that § 201.304(c) will require an average of 4.00 hours of administrative assistant time, 1.50 hours of time each from managers, attorneys, and information technology staff for packers, live poultry dealers, and swine contractors in the first quartile, containing the largest entities, to setup and maintain the required records in the first year. AMS expects the packers, live poultry dealers, and swine contractors in the second quartile will require an average of 2.00 hours of administrative assistant time, 0.75 hours of time each from managers, attorneys, and information technology staff for first year costs. The third quartile will require 1.33 hours of administrative assistant time, 0.50 hours of time each from managers, attorneys, and information technology staff for first year costs, and the fourth quartile, containing the smallest entities, will require 0.67 hours of administrative assistant time, 0.25 hours of time each from managers, attorneys, and information technology staff.

AMS also expects that packers, live poultry dealers, and swine contractors will incur continuing costs in each successive year. AMS estimated that § 201.304(c) will require an average of 3.00 hours of administrative assistant time, 1.50 hours of time each from managers and attorneys, and 1.00 hour of time from information technology staff for packers, live poultry dealers, and swine contractors in the first quartile to setup and maintain the required records in each succeeding year. AMS expects the packers, live poultry dealers, and swine contractors in the second quartile will require an average of 1.50 hours of administrative assistant time, 0.75 hours of time each from managers and attorneys, and 0.50 hours of time from information technology staff in each succeeding year. The third quartile will require 1.00 hour of administrative assistant time, 0.50 hours of time each from managers and attorneys, and 0.33 hours of time from information technology staff in each succeeding year, and the fourth quartile will require 0.50 hours of administrative assistant time, 0.25 hours of time each from managers and attorneys, and 0.17 hours from information technology staff.

Estimated first-year costs for recordkeeping requirements in final § 201.304(c) totaled $11,000 for live poultry dealers,[303] $12,000 for swine contractors,[304] and $111,000 for packers.[305] Estimated yearly continuing costs for recordkeeping requirements in § 201.304(c) totaled $9,000 for live poultry dealers,[306] $10,000 for swine contractors,[307] and $96,000 for packers.[308]

Total expected first year costs for small businesses, including one time reviewing costs and recordkeeping costs will be $192,000 for packers, $37,000 for swine contractors, and $24,000 for live poultry dealers. The table below lists expected costs for small businesses subject to §§ 201.304 and 201.306. AMS expects marginal costs to total $255,000 in the first year. Ten-year costs annualized at three percent will be $107,000 for packers, $13,000 for swine contractors, and $11,000 for live poultry dealers. Total ten-year costs annualized at three percent will be expected to be $131,000.

The table below shows that ten-year costs annualized at seven percent will be $109,000 for packers, $14,000 for swine contractors, and $11,000 for live poultry dealers. Total ten-year costs annualized at seven percent will be expected to be $134,000.

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[303] 10 live poultry dealers × ($44.51 per hour admin. cost × 2 hours + $86.83 per hour manger cost × .75 + $147.19 legal cost × .75 hours + $93.68 information tech cost × .75 hours) + 45 live poultry dealers × ($44.51 per hour admin. cost × (1.33 hours + .67 hours) + $86.83 per hour manger cost × (.5 hours + .25 hours) + $147.19 legal cost × (.5 hours + .25 hours) + $93.68 information tech cost × (.5 hours + .25 hours))/2 = $10,881.

[304] 108 swine contractors × ($44.51 per hour admin. cost × .67 hours + $86.83 per hour manger cost × .25 hours + $147.19 legal cost × .25 hours + $93.68 information tech cost × .25 hours) = $12,053.

[305] 74.25 packers × ($44.51 per hour admin. cost × 2 hours + $86.83 per hour manger cost × .75 hours + $147.19 legal cost × .75 hours + $93.68 information tech cost × .75 hours + 273.75 packers × ($44.51 per hour admin. cost × (2 hours + 1.33 hours + .67 hours) + $86.83 per hour manger cost × (.75 hours + .5 hours + .25 hours) + $147.19 legal cost × (.75 hours + .5 hours + .25 hours) + $93.68 information tech cost × (.75 hours + .5 hours + .25 hours))/3 = $110,817.

[306] 10 live poultry dealers × ($44.51 per hour admin. cost × 1.5 hours + $86.83 per hour manger cost × .75 + $147.19 legal cost × .75 hours + $93.68 information tech cost × .50 hours) + 45 live poultry dealers × ($44.51 per hour admin. cost × (1 hours + .5 hours) + $86.83 per hour manger cost × (.5 hours + .25 hours) + $147.19 legal cost × (.5 hours + .25 hours) + $93.68 information tech cost × (.33 hours + .17 hours))/2 = $9,396.

[307] 108 swine contractors × ($44.51 per hour admin. cost × .5 hours + $86.83 per hour manger cost × .25 hours + $147.19 legal cost × .25 hours + $93.68 information tech cost × .17 hours) = $10,408.

[308] 74.25 packers × ($44.51 per hour admin. cost × 3 hours + $86.83 per hour manger cost × 1.5 hours + $147.19 legal cost × 1.5 hours + $93.68 information tech cost × 1 hours + 273.75 packers × ($44.51 per hour admin. cost × (1.5 hours + 1 hours + .5 hours) + $86.83 per hour manger cost × (.75 hours + .5 hours + .25 hours) + $147.19 legal cost × (.75 hours + .5 hours + .25 hours) + $93.68 information tech cost × (.5 hours + .33 hours + .17 hours))/3 = $110,817.

Table 18: Estimated Industry Total Costs to Small Businesses

Estimate Type	Packers ($)	Swine Contractors ($)	Poultry Processors ($)	Total ($)
First-Year Costs	192,000	37,000	24,000	255,000
10 years Annualized at Three Percent	107,000	13,000	11,000	131,000
10 years Annualized at Seven Percent	109,000	14,000	11,000	134,000

Live poultry dealers annually file reports with AMS that list each firm's net sales. Packers that purchase more than $500,000 annually in livestock also file annual reports that list net sales. While packers that annually slaughter less than $500,000 in livestock also file annual reports with AMS, in order to reduce the reporting requirements for small packers, they are not required to provide annual net sales.

Data from the annual reports enables AMS to compare average net sales for small pork packers, beef packers, and live poultry dealers to the expected costs of §§ 201.304 and 201.306 in the table below. A shortcoming in the comparison is that net sales for smallest packers, those that purchase less than $500,000 in livestock, are not included in the average.

Swine contractors are not required to file annual reports with AMS, and similar net sales data are not available for swine contractors. Census of Agriculture's data have the number of head sold by size classes for farms that sold their own hogs and pigs in 2017 and that identified themselves as contractors or integrators, but not the value of sales nor the number of head sold from the farms of the contracted production. To estimate average revenue per establishment, AMS used the estimated average value per head for sales of all swine operations and the production values for firms in the Agriculture Census size classes for swine contractors.

Table 19 compares the average per entity first-year costs of final §§ 201.304 and 201.306 to the average revenue per establishment for all regulated small businesses. First-year costs are appropriate for a threshold analysis because all the costs will occur in the first year. First-year costs per regulated entity are considerably higher than annualized costs, and any ratio of annualized costs to revenues will be less than a ratio of first-year costs to revenues.

Table 19: Comparison of Average Costs per Entity to Average Revenues per Entity for Small Businesses

NAICS	No. of Small Businesses	Average Revenue or Net Sales Per Establishment ($)	Average First-Year Costs ($)	Average First-Year Cost as Percent of Revenue (percent)	Annualized Cost Discounted at 7 Percent	Annualized Cost as Percent of Revenue (percent)
112210 - Swine Contractor	108	485,860	346	0.0711	130	0.0267
311615 – Poultry Processor	55	52,888,111	432	0.0008	206	0.0004
311611 – Meat Packer*	348	75,838,951	552	0.0007	312	0.0004

*Averages exclude net sales for packers that purchased less than $500,000 in livestock annually.

Average first-year costs as a percent of revenues are small. It is highest for swine contractors because average revenues for swine contractors are considerably smaller than average revenues for packers and live poultry dealers. At 0.0711 percent, the average first-year cost is small compared to revenue.

Average net sales for packers listed in Table 18 have the problem of excluding the smallest packers, and consequently the averages are biased toward being too large. However, first-year cost as a percent of net sales is 0.0007 percent. Estimated first year cost for each packer is $552. These are relatively small numbers. If average net sales for each packer were only one hundredth of the amount listed in Table 19, estimated average first-year costs will be less than 0.1 percent of net sales.

AMS has limited data on revenues for the smallest packers and live poultry dealers. One hundred eleven packers submitted shortened annual reports to AMS because they purchased less than $500,000 in livestock. For the largest of these small packers, annual revenues are likely close to $500,000 and expected costs will be about 0.07 percent.

RFA Small Business Exemption Alternative: Recordkeeping Exemption

AMS also considered a Small Business Exemption Alternative to final §§ 201.304 and 201.306. The Small Business Exemption Alternative will be the same as the final §§ 201.304 and 201.306 in all respects with the exception that none of the recordkeeping requirements in § 201.304(c) will apply to small businesses. This Small Business Exemption Alternative will cost small packers, swine contractors, and live poultry dealers less than §§ 201.304 and 201.306 will cost. Recordkeeping costs comprised the largest share of the costs associated with §§ 201.304 and 201.306.

Although the Small Business Exemption Alternative will not require small businesses to keep any additional records, small businesses will still be required to comply with all the other provisions of §§ 201.304 and 201.306. AMS expects that small live poultry dealers, small packers, and small swine contractors will need to review the new rule and determine whether the rule will require any changes to their procurement contracts or other business practices and make the necessary changes. AMS estimated that costs will consist of one hour of a manager's time and one hour of a lawyer's time to review the requirements of final §§ 201.304 and 201.306. This amounts to expected first-year costs of $234 [309] for each live poultry dealer, each swine contractor, and each packer that qualifies as a small business. All costs will occur in the first year.

The table below lists expected costs for small businesses subject to the Small Business Exemption Alternative. AMS expects marginal costs to total $120,000 in the first year. The Small Business Exemption Alternative is expected to cost $81,000, $25,000, and $13,000 in the first year for packers, swine contractors, and live poultry dealers, respectively.

Table 20: Estimated Industry Total Costs for the Small Business Exemption Alternative

Estimate Type	Packers ($)	Swine Contractors ($)	Poultry Processors ($)	Total Costs* ($)
First-Year Costs	81,000	25,000	13,000	120,000
10 years Annualized at Three Percent	9,000	3,000	1,000	14,000
10 years Annualized at Seven Percent	11,000	3,000	2,000	16,000

*Due to rounding, values in "Total Costs" column may not match the sum of costs by entity type.

[309] $147.19 per hour × 1 hour of an attorney's time + $86.83 per hour × 1 hour of a manager's time = $234.

Ten-year costs annualized at three percent will be $9,000 for packers, $3,000 for swine contractors, and $1,000 for live poultry dealers. This amounts to $27 for each live poultry dealer, swine contractor, and packer. Total ten-year costs annualized at three percent will be expected to be $14,000.

Ten-year costs annualized at seven percent will be $11,000 for packers, $3,000 for swine contractors, and $2,000 for live poultry dealers. This amounts to $31 for each live poultry dealer, swine contractor, and packer. Total ten-year costs annualized at seven percent will be expected to be $16,000.

The table below compares the average per entity first-year costs of the Small Business Exemption Alternative to the average revenue for each regulated small business. First-year costs are appropriate for a threshold analysis because all the costs associated with the alternative will occur in the first year.

Table 21: Comparison of Per Entity Cost to Revenues for the Small Business Exemption Alternative

NAICS	No. of Small Businesses	Average First-Year Costs ($)	Average Revenue or Net Sales Per Establishment ($)	Average First-Year Cost as Percent of Revenue (percent)
112210 - Swine Contractor	108	234	485,860	0.0482
311615 – Poultry Processor	55	234	52,888,111	0.0004
311611 – Meat Packer*	348	234	75,838,951	0.0003

*Averages exclude net sales for packers that purchased less than $500,000 in livestock annually.

Average first-year costs as a percent of revenues are small. Similar to §§ 201.304 and 201.306, relative costs are highest for swine contractors because average revenues for swine contractors are considerably smaller than average revenues for packers and live poultry dealers. At 0.0482 percent, the first-year cost to swine contractors is small compared to revenue.

Average net sales for packers listed in Table 20 have the same problem as the net sales figures in Table 18. They exclude the smallest packers, and consequently the averages are biased toward being too large. However, first-year cost as a percent of net sales for packers purchasing more than $500,000 per year is 0.0002 percent. Estimated first year cost for each packer is $234. Costs will be less than 0.1 percent of revenues for any packer with revenue greater than $23,400. Even for the smallest packer that AMS regulates, $234 will not likely have a significant economic impact.

Comparison of Alternatives

Expected costs for small businesses under final §§ 201.304 and 201.306 will be more than double the expected costs for small businesses under a Small Business Exemption Alternative. The cost difference is due to recordkeeping requirements. First-year costs will be $159,000 more for final §§ 201.304 and 201.306 than the Small Business Exemption Alternative.[310] While all the costs associated with the Small Business Exemption Alternative occur in the first year, small businesses will continue to incur recordkeeping costs associated with final §§ 201.304 and 201.306 into the future. Estimated costs annualized at seven percent are $121,000 higher for final §§ 201.304 and 201.306 than for the Small Business Exemption Alternative.

With either the Small Business Exemption Alternative or the final rule, AMS expects the costs per entity to be relatively small. The number of regulated entities that could experience a cost increase is substantial. Most regulated packers and live poultry dealers are small businesses. However, AMS expects that few small businesses will experience significant costs. For all three groups of regulated entities: packers, live poultry dealers, and swine contractors, average first year costs are expected to amount to less than 0.1 percent of annual revenue for either of the alternatives. AMS expects that any additional costs to small packers, live poultry dealers, and swine contractors from this rulemaking will not change their ability to continue operations or place any small businesses at a competitive disadvantage.

AMS chose final §§ 201.304 and 201.306 over the Small Business Exemption Alternative because AMS wishes to prevent the kind of undue prejudices and unjust discrimination described in the rule. AMS believes that keeping relevant records serves as constant reminder to all packers, live poultry dealers, and swine contractors that they cannot practice undue prejudice on the basis of protected bases and protected actions; retaliate on the basis of protected activities or actions; or deceive on the basis of contract formation, performance, termination, or refusal.

Final §§ 201.304 and 201.306 are not expected to have a significant economic impact on a substantial number of small business entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

E.O. 13175 requires Federal agencies to consult with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Three commenters including the Cherokee Nation, the Coalition of Large Tribes (COLT), and an academic commenter who is the executive

[310] $586,000 – $427,000 = $159,000 (Table 15).

director of the Indigenous Food and Agriculture Initiative (IFAI) at the University of Arkansas School of Law, responded to USDA's January 19, 2023, Tribal consultation seeking input on the proposed rule on Inclusive Competition and Market Integrity Under the Act. All three commenters gave context about Tribal participation in the meat and livestock industry and contended that the proposed rule should not apply to Tribes and Tribal entities.

Comment: A commenter stated that the proposed rule's provisions targeting unjust discrimination could inadvertently ban practices designed to enable Tribal enterprises to serve their own community, such as laws requiring businesses to provide contracting and employment preferences to Tribal members. According to the commenter, these practices could arguably be interpreted under the proposed rule as ''offering contract terms that are less favorable than those generally or ordinarily offered'' or ''differential contract performance or enforcement'' which are ''based upon the covered producer's status as a market vulnerable individual.'' According to the commenter, the regulation's language, as proposed, and the lack of exceptions provided could have a chilling effect on the traditional animal husbandry practices of Tribes regardless of a Tribal business's likelihood of prevailing under a legal challenge.

AMS Response: In its final rule, AMS has included a limited list of legitimate business justifications including an exception to the rule's prohibition on unjust discrimination for Tribes fulfilling their governmental function of serving their members. In doing so, AMS in this rule recognizes longstanding practice around Tribal entities, acting in their governmental capacities, in preferencing their own Tribal members and their descendants in the purchase and sale of livestock. Additionally, AMS has changed its approach from the proposed rule to no longer use the term ''Market Vulnerable'' to define to whom the rule offers protections. In shifting to the specific terms identified, the final rule provides greater certainty that Tribal members will be protected against discriminatory practices they may encounter in the marketplace.

Comment: A Tribal commenter stated that Tribal producers may be hesitant to report discriminatory practices, stating that the long history of governmental indifference to, or even complicity in, unjust discrimination against their communities' factors into a fear of retaliation. The commenter noted Tribal producers have also reported that they are not sure where to report violations of the Act, suggesting USDA should consider establishing a streamlined process for reporting issues under the Act and make concerted efforts to inform producers of their rights.

AMS Response: Through expressly prohibiting discriminatory and retaliatory conduct in this rulemaking, AMS aims to address the commenters concern that ''a long history of governmental indifference to, or even complicity in, discrimination against their communities' factors into a fear of retaliation.'' AMS has an online portal designed to receive complaints that may amount to violations under the Act and will direct Tribal producers to this portal as well as educating them as to other methods of reporting potential violations. Furthermore, AMS will consult with the USDA Office of Tribal Relations (OTR) and recommend educational outreach to ensure Tribal producers understand how to report a violation.

Comment: All three commenters urged AMS not to apply the proposed rule to Tribes and Tribal entities. The commenters said Tribes are sovereign governments that retain authority to make their own laws and be ruled by them, unless expressly abrogated. Commenters cited the Supreme Court's holding in *Vermont Agency of Natural Resources* v. *United States ex rel. Stevens* that statutory use of the term ''person'' does not include sovereign entities unless there is an ''affirmative showing of statutory intent to the contrary,'' arguing that Tribes do not fall within any of these categories.[311] Commenters said the omission of Tribes from the ''person'' definition also excludes them from being defined as ''packers'' under the Act, as it defines packers as ''any person engaged in'' the packing activities enumerated in the definition.

AMS Response: In this final rule, AMS excludes Tribes that are fulfilling their governmental function of serving their members from the rule's prohibition on unjust discrimination. In doing so, AMS recognizes the longstanding practice of Tribal entities, acting in their governmental capacities, in preferencing their own Tribal members and their descendants in the purchase and sale of livestock. AMS believes that these changes are sufficient to address the immediate policy concerns underlying the comments in relation to this final rule and that any further changes would be outside the scope of this rule.

[311] *See Vermont Agency of Natural Resources* v. *United States ex rel. Stevens*, 529 U.S. 765 (2000).

Comment: Commenters stated that ''complying with unnecessary and burdensome federal regulations will hinder our small Tribal agricultural operations that already operate on very thin margins.'' Arguing that given the small size of packing operations on Tribal land, they may lack the resources or financial ability to comply with recordkeeping and other regulatory requirements the rule imposes. A commenter stated that ''record keeping, and other regulatory obligations are always more burdensome to small businesses that lack the legal and compliance departments of a large corporation, and isolated rural locations often struggle to hire and retain adequate office staff.''

AMS Response: The economic costs of preventing undue prejudice, unjust discrimination, retaliation, and deception are minor in comparison to the benefit such protections will ensure for farmers and ranchers, including Tribal members. Many businesses already keep records for business purposes, therefore adding hardly any additional costs associated with compliance with this rule. Furthermore, Tribal commenters state that discrimination and retaliation are commonplace in Indian country and that these harms greatly hinder the success of Tribal producers. This rule aims to address those issues directly. AMS notes that the final rule excludes Tribes fulfilling their governmental function of serving their members from the rule's prohibition on unjust discrimination and that any further changes would be outside the scope of this rule.

Comment: Commenters stated that under Federal jurisprudence, sovereign immunity extends to business activities conducted off Tribal lands. Commenters contend that the U.S. Supreme Court has determined in *Oklahoma Tax Commission* v. *Citizen Band Potawatomi Indian Tribe of Oklahoma,* 498 U.S. 505 (1991) decision, that Tribes in their commercial activity with other entities are covered under the umbrella of the Tribes' sovereignty and even when Tribes entered into activities, executed off-reservation, they still enjoy sovereign immunity *Kiowa Tribe of Oklahoma* v. *Manufacturing Technologies,* 523 U.S. 751 (1998). *See Garcia* v. *San Antonio Metro. Transit Auth.,* 469 U.S. 528, 546–47 (1985).

AMS Response: AMS notes that the final rule excludes Tribes fulfilling their governmental function of serving its members from the rule's prohibition on unjust discrimination. Any further changes would be outside the scope of this rule.

Comment: A commenter suggests that if adopted and applied to Tribal entities, the rule would have an adverse effect to its intent. Stating that if the intent of the proposed rule is to decrease market concentration and increase market access, adding additional regulatory burdens on small scale meat packing plants will make it more difficult for these small operations to enter, and maintain presence in, the market.

AMS Response: The overarching objective of this rule is to improve market integrity and inclusive competition, and to decrease the undesirable conduct that is facilitated by concentration in agricultural markets. This rule aims to address three specific types of conduct that harm competition: undue prejudice and unjust discrimination, retaliation, and deception. As explained in the RIA/RFA, any regulatory burdens created from enforcing the Act in this regard will be minimal in comparison to the benefits of protecting producers from this harmful conduct. AMS notes that the final rule excludes Tribes fulfilling their governmental function of serving their members from the rule's prohibition on unjust discrimination and that any further changes would be outside the scope of this rule.

D. Civil Rights Impact Statement

Objective and Purpose AMS is issuing this final rule to revise the regulations that effectuate the Act. AMS is adopting these regulations under the Act's provisions prohibiting undue prejudice, unjust discrimination, and deception to establish clearer, more effective standards to govern the modern marketplace and to better protect, through compliance and enforcement, individually harmed producers. AMS is concerned that the current regulations do not adequately address many unduly prejudicial, unjustly discriminatory, retaliatory, and deceptive practices, which are exacerbated by the environment created through increased horizontal concentration and vertical contracting.

Who Is Impacted—The effects of this new regulation will fall on packers, swine contractors and live poultry dealers. AMS will cite regulated entities initiating actions or conduct. AMS believes creating an undue prejudice is a violation of section 202(b) of the Act. This is particularly true for those purchasing livestock on a carcass grade, carcass weight, or carcass grade and weight basis, under marketing agreements and production contracts. Swine contractors obtaining swine under swine production contracts and live poultry dealers acquiring poultry through poultry growing arrangements will also feel the impacts of the new regulation.

Beneficiaries—The primary beneficiaries of §§ 201.304 and 201.306 will include farmers, feedlot owners, swine production contract growers, and poultry growers. These producers and growers are those most likely to be harmed by undue prejudices, unjust discrimination, retaliation, and deception resulting from the actions or conduct of firms subject to the Act. Identifying criteria for recognizing what actions or conduct may create undue prejudices, discrimination, retaliation, and deception will help lower the number of instances and severity of the harm done by these types of actions or conduct.

The Civil Rights Impact Analysis found that Asian, and Native Hawaiians or Other Pacific Islanders are disproportionately impacted by this rule. Other impacted producers, including Men, Women, Hispanics, Whites, Black/African Americans, and American Indians, are not disproportionately impacted by this rule.

Impacts on Regulated Entities—AMS estimated the direct and indirect costs of regulation over a period of 10 years, from 2023 through 2032. AMS expects the direct costs to be comprised of administrative and litigation costs, largely borne by regulated entities.

Impacts on Protected Groups—Protected groups will see minimal, if any, direct or indirect costs because of the implementation or enforcement of the new regulations. Although the required analysis indicates a disproportionate impact for Asian, and Native Hawaiians or Other Pacific Islanders, because the new regulations impact all industry participants equally, no individual or group would likely be adversely impacted.

AMS has considered the potential civil rights implications of this final rule on members of protected groups to ensure that no person or group will be adversely or disproportionately at risk or discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, or protected genetic information.

Tribal Implications—Executive Order 13175 requires Federal agencies to consult with American Indian Tribes on a government-to-government basis on policies that have Tribal implications. This includes regulations, legislative comments or proposed legislation, and other policy statements or actions. Consultation is required when such policies have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes.

AMS has determined that this final rule does not have substantial direct effects on one or more Tribes that would require consultation. If a Tribe requests consultation, AMS will work with USDA's Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress. AMS will also conduct outreach to ensure that Tribes and Tribal members are aware of the requirements and benefits under this final rule.

Positive Impacts—This final rule affirms the importance of a clear and direct regulatory framework that prohibits deception, retaliation, undue prejudice, and unjust discrimination, thus protecting producers in the marketplace. The rational decision-making and robust competition so critical to economic success can most effectively occur in a market free of such practices.

To ensure the potential disparately impacted groups identified above receive the full measure of the positive impacts of this new regulation, AMS will provide addition outreach actions directed toward these groups.

E. Executive Order 12988—Civil Justice Reform

This rule has been reviewed under Executive Order 12988. This rule is not intended to have retroactive effect. This rule would not preempt State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rulemaking. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule. Nothing in this rule is intended to interfere with a person's right to enforce liability against any person subject to the Act under authority granted in section 308 of the Act.

F. E-Government Act

USDA is committed to complying with the E-Government Act by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

G. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L.

104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal Governments and on the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures of $100 million or more (adjusted for inflation) in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in title II of UMRA, for State, local, or Tribal Governments, and it does not contain a mandate for the private sector that would likely result in compliance costs of $100 million or more (adjusted annually for inflation) in at least one year. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

AMS expects that the direct costs of this final rule will be 0.0002 percent of industry revenues in the first year of the rule, or $586,000. Indirect costs would have to be nearly 300 times [312] the expected direct costs to meet the compliance cost threshold of $170 million or more in a single year ($100 million in 1994 dollars adjusted for inflation as of 2021),[313] which AMS has no basis to expect, given its professional expertise gained by regulating the industry and regularly communicating with regulated entities, growers, and producers. Indeed, to reach that threshold, discrimination, retaliation, and deception would have to occur at a prevalence that would have to touch more than 28 percent of all cattle slaughtered in the United States in 2022 and account for the *entirety* of the difference in prices between the minimum and average liveweight price paid for cattle at the five regional cattle markets over the last 9 years. Extending that analysis to poultry and hogs would not change the conclusion. If anything, it would be even harder to meet the UMRA threshold because almost universal use of the tournament system in the poultry industry means higher compensation to certain growers is unlikely to increase compensation for growers in aggregate. Each tournament has a fixed total compensation pool, with growers ranked relative to other members of their respective tournament and compensated accordingly.

In addition, AMS takes note of the exemption from UMRA for rules enforcing Constitutional rights of individuals or establishing or enforcing a statutory right that prohibits discrimination on the basis of age, race, color, religion, sex, national origin, handicap, or disability. (2 U.S.C. 1503) Provisions of this rule enforce the Act's prohibition against unjust discrimination and undue prejudice to prohibit adverse treatment on the basis of race, color, religion, national origin (including ethnicity), sex (including sexual orientation and gender identity, as well as pregnancy), disability, marital status, or age. The rule also prohibits retaliatory and adverse actions that interfere with lawful communications, assertion of rights, associational participation, and other protected activities.

H. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this final rule does not meet the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 9 CFR Part 201

Confidential business information, Reporting and recordkeeping requirements, Stockyards, Surety bonds, Trade practices.

For the reasons set forth in the preamble, AMS amends 9 CFR part 201 as follows:

PART 201—ADMINISTERING THE PACKERS AND STOCKYARDS ACT

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 7 U.S.C. 181–229c.

■ 2. Add subpart O, consisting of §§ 201.300 through 201.390, to read as follows:

Subpart O—Competition and Market Integrity

Sec.

Subpart O—Competition and Market Integrity

§§ 201.300–201.301 [Reserved]

§ 201.302 Definitions.

For purposes of this subpart, the following definitions apply:

Covered producer means a livestock producer as defined in this section or a swine production contract grower or poultry grower as defined in section 2(a) of the Act (7 U.S.C. 182(8), (14)).

Livestock producer means any person, except an employee of the livestock owner, engaged in the raising of and caring for livestock.

Regulated entity means a swine contractor or live poultry dealer as defined in section 2(a) of the Act (7 U.S.C. 182(8)) or a packer as defined in section 201 of the Act (7 U.S.C. 191).

§ 201.303 [Reserved]

§ 201.304 Undue prejudices or disadvantages and unjust discriminatory practices.

(a) *Prohibited bases.* (1) Except as provided in paragraph (a)(3) of this section, a regulated entity may not prejudice, disadvantage, inhibit market access, or otherwise take an adverse action against a covered producer with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry based upon the following characteristics:

(i) On the basis of the covered producer's race, color, religion, national origin, sex (including sexual orientation and gender identity), disability, marital status, or age.

(ii) On the basis of the covered producer's status as a cooperative.

(2) Actions that prejudice, disadvantage, inhibit market access, or are otherwise adverse under paragraph (a)(1) of this section are as follows:

(i) Offering contract terms that are less favorable than those generally or ordinarily offered to similarly situated covered producers.

(ii) Refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers.

(iii) Performing under or enforcing a contract differently than with similarly situated covered producers.

(iv) Requiring a contract modification or renewal on terms less favorable than similarly situated covered producers.

(v) Terminating or not renewing a contract.

(vi) Any other action that a reasonable covered producer would find materially adverse.

(3) The following actions by a regulated entity do not prejudice,

[312] $170 million UMRA threshold divided by $586,000 (first-year direct costs) multiplied by 100 = 290.

[313] Congressional Research Service. Updated February 23, 2021. Unfunded Mandates Reform Act: History, Impact, and Issues. Accessed at *https://crsreports.congress.gov/product/pdf/R/R40957/109on02/08/2024.*

disadvantage, inhibit market access, or constitute adverse action under paragraph (a)(1) of this section:

(i) Fulfilling a religious commitment relating to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry.

(ii) A Federally recognized Tribe, including its wholly or majority-owned entities, corporations, or Tribal organizations, performing its Tribal governmental functions.

(b) *Retaliation prohibited.* (1) A regulated entity may not retaliate or otherwise take an adverse action against a covered producer based upon the covered producer's participation in an activity described in paragraph (b)(2) of this section.

(2) The following activities by covered producers are protected under paragraph (b)(1) of this section unless otherwise prohibited by Federal, Tribal, or State law, including antitrust laws:

(i) Communicating with a government entity or official or petitioning a government entity or official for redress of grievances with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry.

(ii) Refusing a request of the regulated entity to engage in a communication with a government entity or official that is not required by law.

(iii) Asserting the right to form or join, or to refuse to form or join, a producer or grower association or organization, or cooperative or to collectively process, prepare for market, handle, or market livestock or poultry.

(iv) Communicating or cooperating with a person for the purposes of improving production or marketing of livestock or poultry.

(v) Communicating, negotiating, or contracting with a regulated entity, another covered producer, or with a commercial entity or consultant, for the purpose of exploring or entering into a business relationship.

(vi) Supporting or participating as a witness in any proceeding under the Act, or any proceeding that relates to an alleged violation of any law by a regulated entity.

(vii) Asserting any of the rights granted under Act or this part, or asserting contract rights.

(3) The following actions are considered retaliation or an otherwise adverse action under paragraph (b)(1) of this section:

(i) Terminating or not renewing a contract.

(ii) Performing under or enforcing a contract differently than with similarly situated covered producers.

(iii) Requiring a contract modification or a renewal on terms less favorable than similarly situated covered producers.

(iv) Refusing to deal with a covered producer on terms generally or ordinarily offered to similarly situated covered producers.

(v) Interfering in a farm real estate transaction or a contract with third parties.

(vi) Any other action that a reasonable covered producer would find materially adverse.

(c) *Recordkeeping of compliance practices.* (1) The regulated entity shall retain all records relevant to its compliance with paragraphs (a) and (b) of this section for no less than 5 years from the date of record creation.

(2) Relevant records to paragraph (c)(1) of this section may include: policies and procedures, staff training materials, materials informing covered producers regarding reporting mechanisms and protections, compliance testing, board of directors' oversight materials, and the number and nature of complaints received relevant to this section.

§ 201.305 [Reserved]

§ 201.306 Deceptive practices.

(a) *Prohibited practices.* A regulated entity may not engage in the deceptive practices in paragraphs (b) through (e) of this section with respect to livestock, meats, meat food products, livestock products in unmanufactured form, or live poultry.

(b) *Contract formation.* A regulated entity may not make or modify a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading.

(c) *Contract performance.* A regulated entity may not perform under or enforce a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading.

(d) *Contract termination.* A regulated entity may not terminate a contract with a covered producer by employing a false or misleading statement, or omission of material information necessary to make a statement not false or misleading.

(e) *Contract refusal.* A regulated entity may not provide false or misleading information to a covered producer or association of covered producers concerning a refusal to contract.

§§ 201.307—201.308 [Reserved]

§ 201.389 [Reserved]

§ 201.390 Severability.

If any provision of this subpart, or any component of any provision, is declared invalid or the applicability thereof to any person or circumstances is held invalid, it is the Agricultural Marketing Service's intention that the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby with the remaining provision, or component of any provision, to continue in effect.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–04419 Filed 3–5–24; 8:45 am]

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Part III

Environmental Protection Agency

40 CFR Parts 50, 53, and 58
Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 53, and 58

[EPA–HQ–OAR–2015–0072; FRL–8635–02–OAR]

RIN 2060–AV52

Reconsideration of the National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) reconsideration of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA is revising the primary annual $PM_{2.5}$ standard by lowering the level from 12.0 μg/m^3 to 9.0 μg/m^3. The Agency is retaining the current primary 24-hour $PM_{2.5}$ standard and the primary 24-hour PM_{10} standard. The Agency also is not changing the secondary 24-hour $PM_{2.5}$ standard, secondary annual $PM_{2.5}$ standard, and secondary 24-hour PM_{10} standard at this time. The EPA is also finalizing revisions to other key aspects related to the PM NAAQS, including revisions to the Air Quality Index (AQI) and monitoring requirements for the PM NAAQS.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0072. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Lars Perlmutt, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–04, Research Triangle Park, NC 27711; telephone: (919) 541–3037; fax: (919) 541–5315; email: *perlmutt.lars@epa.gov.*

SUPPLEMENTARY INFORMATION:

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The following topics are discussed in this preamble:

Executive Summary

This document presents the Administrator's final decisions for the reconsideration of the 2020 final decision on the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). More specifically, this document summarizes the background and rationale for the Administrator's final decisions to revise the primary annual $PM_{2.5}$ standard by lowering the level from 12.0 μg/m^3 to 9.0 μg/m^3; to retain the current primary 24-hour $PM_{2.5}$ standard (at a level of 35 μg/m^3); to retain the primary 24-hour PM_{10} standard; and, not to change the secondary PM standards at this time. In reaching his final decisions, the Administrator considered the currently available scientific evidence in the 2019 Integrated Science Assessment (2019 ISA) and the Supplement to the 2019 ISA (ISA Supplement), quantitative and policy analyses presented in the 2022 Policy Assessment (2022 PA), advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposal. The EPA has established primary and secondary standards for $PM_{2.5}$, which includes particles with diameters generally less than or equal to 2.5 μm, and PM_{10}, which includes particles with diameters generally less than or equal to 10 μm. The standards include two primary $PM_{2.5}$ standards: an annual average standard, averaged over three years, with a level of 12.0 μg/m^3, and a 24-hour standard with a 98th percentile form, averaged over three years, and a level of 35 μg/m^3. It also includes a primary PM_{10} standard with a 24-hour averaging time, and a level of 150 μg/m^3, not to be exceeded more than once per year on average over three years. Secondary PM standards are set equal to the primary standards, except that the level of the secondary annual $PM_{2.5}$ standard is 15.0 μg/m^3.

The most recent of the PM NAAQS was completed in December 2020. In that review, the EPA retained the primary and secondary NAAQS, without revision (85 FR 82684, December 18, 2020). Following publication of the 2020 final action, several parties filed petitions for review and petitions for reconsideration of the EPA's final decision.

In June 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action.[1] The EPA decided to reconsider the December 2020 decision because the available scientific evidence and technical information indicated that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act. The EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary $PM_{2.5}$ standards and supported consideration of revising the level of the primary annual $PM_{2.5}$ standard to below the current level of 12.0 μg/m^3 while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020b). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information did not call into question the adequacy of the primary PM_{10} or secondary PM standards and supported consideration of retaining the primary PM_{10} standard and secondary PM standards without revision (U.S. EPA, 2020b).

The final decisions presented in this document on the primary $PM_{2.5}$ standards have been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA and ISA Supplement, quantitative exposure/risk analyses and policy evaluations presented in the 2022 PA, advice from the CASAC[2] and public comment received as part of this reconsideration.[3] The health effects evidence newly available in this reconsideration, in conjunction with the full body of evidence critically evaluated in the 2019 ISA, supports a causal relationship between long- and short-term exposures and mortality and cardiovascular effects, and the evidence supports a likely to be a causal relationship between long-term exposures and respiratory effects, nervous system effects, and cancer. The longstanding evidence base, including animal toxicological studies, controlled human exposure studies, and epidemiologic studies, reaffirms, and in some cases strengthens, the conclusions from past reviews regarding the health effects of $PM_{2.5}$ exposures. Epidemiologic studies available in this reconsideration demonstrate generally positive, and often statistically significant, $PM_{2.5}$ health effect associations. Such studies report associations between estimated $PM_{2.5}$ exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (*e.g.,* lung cancer mortality or incidence, asthma development). The scientific evidence available in this reconsideration, as evaluated in the 2019 ISA and ISA Supplement, includes

[1] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged.*

[2] In 2021, the Administrator announced his decision to reestablish the membership of the CASAC. The Administrator selected seven members to serve on the chartered CASAC, and appointed a PM CASAC panel to support the chartered CASAC's review of the draft ISA Supplement and the draft PA as a part of this reconsideration (see section I.C.6.b below for more information).

[3] More information regarding the CASAC review of the draft ISA Supplement and the draft PA, including opportunities for public comment, can be found in the following **Federal Register** notices: 86 FR 54186, September 30, 2021; 86 FR 52673, September 22, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022.

a number of epidemiologic studies that use various methods to characterize exposure to $PM_{2.5}$ (*e.g.,* ground-based monitors and hybrid modeling approaches) and to evaluate associations between health effects and lower ambient $PM_{2.5}$ concentrations. There are a number of recent epidemiologic studies that use varying study designs that reduce uncertainties related to confounding and exposure measurement error. The results of these analyses provide further support for the robustness of associations between $PM_{2.5}$ exposures and mortality and morbidity. Moreover, the Administrator notes that recent epidemiologic studies strengthen support for health effect associations at lower $PM_{2.5}$ concentrations, with these new studies finding positive and significant associations when assessing exposure in locations and time periods with lower annual mean and 25th percentile concentrations than those evaluated in epidemiologic studies available at the time of previous reviews. Additionally, the experimental evidence (*i.e.,* animal toxicological and controlled human exposure studies) strengthens the coherence of effects across scientific disciplines and provides additional support for potential biological pathways through which $PM_{2.5}$ exposures could lead to the overt population-level outcomes reported in epidemiologic studies for the health effect categories for which a causal relationship (*i.e.,* short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects) or likely to be causal relationship (*i.e.,* short- and long-term $PM_{2.5}$ exposure and respiratory effects; and long-term $PM_{2.5}$ exposure and nervous system effects and cancer) was concluded.

The available evidence in the 2019 ISA continues to provide support for factors that may contribute to increased risk of $PM_{2.5}$-related health effects including lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and socioeconomic status. For example, the 2019 ISA and ISA Supplement conclude that there is strong evidence that Black and Hispanic populations, on average, experience higher $PM_{2.5}$ exposures and $PM_{2.5}$-related health risks than non-Hispanic White populations. In addition, studies evaluated in the 2019 ISA and ISA Supplement also provide evidence indicating that communities with lower socioeconomic status (SES), as assessed in epidemiologic studies using indicators of SES including income and educational attainment are, on average, exposed to higher concentrations of $PM_{2.5}$ compared to higher SES communities.

The quantitative risk assessment, as well as policy considerations in the 2022 PA, also inform the final decisions on the primary $PM_{2.5}$ standards. The risk assessment in this reconsideration focuses on all-cause or nonaccidental mortality associated with long- and short-term $PM_{2.5}$ exposures. The primary analyses focus on exposure and risk associated with air quality that might occur in an area under air quality conditions that just meet the current and potential alternative standards. The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated premature deaths in the United States, and that public health improvements would be associated with just meeting all of the alternative (more stringent) annual and 24-hour standard levels modeled. Additionally, the results of the risk assessment suggest that for most of the U.S., the annual standard is the controlling standard and that revision to that standard has the most potential to reduce $PM_{2.5}$ exposure-related risk. The analyses are summarized in this document and in the proposal and are described in detail in the 2022 PA.

In its advice to the Administrator, in its review of the 2021 draft PA, the CASAC concurred that the currently available health effects evidence calls into question the adequacy of the primary annual $PM_{2.5}$ standard. With regard to the primary annual $PM_{2.5}$ standard, the majority of the CASAC concluded that the level of the standard should be revised within the range of 8.0 to 10.0 $\mu g/m^3$, while the minority of the CASAC concluded that the primary annual $PM_{2.5}$ standard should be revised to a level of 10.0 to 11.0 $\mu g/m^3$. With regard to the primary 24-hour $PM_{2.5}$ standard, the CASAC did not reach consensus on the adequacy of the current standard. The majority of the CASAC concluded that the primary 24-hour $PM_{2.5}$ was not adequate and that the level of the standard should be revised to within the range of 25 to 30 $\mu g/m^3$, while the minority of the CASAC concluded that the standard was adequate and should be retained, without revision. Additionally, in their review of the 2019 draft PA, the CASAC did not reach consensus on the adequacy of the primary annual $PM_{2.5}$ standard, with the minority recommending revision and the majority recommending the standard be retained. In their review of the 2019 draft PA, the CASAC reached consensus regarding the adequacy of the primary 24-hour $PM_{2.5}$ standard, concluding that the standard should be retained.

In considering how to revise the suite of primary $PM_{2.5}$ standards to provide the requisite degree of protection, the Administrator recognizes that the current annual standard and 24-hour standard, together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. Further, he recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations.

As in 2012, the Administrator concludes that the most effective way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures is to set a generally controlling annual standard, and to provide supplemental protection against the occurrence of peak 24-hour $PM_{2.5}$ concentrations by means of a 24-hour standard set at the appropriate level. Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comments, the Administrator concludes that the current primary annual $PM_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety. The Administrator notes that the CASAC was unanimous in its advice on the 2021 draft PA regarding the need to revise the annual standard. In considering the appropriate level for a revised annual standard, the Administrator concludes that a standard set at a level of 9.0 $\mu g/m^3$ reflects his judgment about placing the most weight on the strongest available evidence while appropriately weighing the uncertainties.

With regard to the primary 24-hour $PM_{2.5}$ standard, the Administrator finds the available scientific evidence and quantitative information to be insufficient to call into question the adequacy of the public health protection afforded by the current 24-hour standard. He further notes that a more stringent annual standard set at a level of 9.0 $\mu g/m^3$ is expected to reduce both average (annual) concentrations and peak (daily) concentrations. The Administrator also notes that, in their review of the 2021 draft PA, the CASAC did not reach consensus on whether revisions to the primary 24-hour $PM_{2.5}$ standard are warranted at this time. He also notes that, in their review of the 2019 draft PA, the CASAC did reach consensus that the primary 24-hour $PM_{2.5}$ standard should be retained. The Administrator concludes that the 24-hour standard should be retained to

continue to provide requisite protection against short-term peak $PM_{2.5}$ concentrations, particularly when considered in conjunction with the protection provided by the suite of standards and the decision to revise the annual standard to a level of 9.0 μg/m³.

The primary PM_{10} standard is intended to provide public health protection against health effects related to exposures to $PM_{10–2.5}$, which are particles with a diameter between 10 μm and 2.5 μm. The final decision to retain the current 24-hour PM_{10} standard has been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA, the policy evaluations presented in the 2022 PA, advice from the CASAC and public comments. Specifically, the health effects evidence for $PM_{10–2.5}$ exposures is somewhat strengthened since past reviews, although the strongest evidence still only provides support for a suggestive of, but not sufficient to infer, causal relationship with long- and short-term exposures and mortality and cardiovascular effects, short-term exposures and respiratory effects, and long-term exposures and cancer, nervous system effects, and metabolic effects. In reaching his final decision on the primary PM_{10} standard, the Administrator recognizes that, while the available health effects evidence has expanded, recent studies are subject to the same types of uncertainties that were judged to be important in previous reviews. He also recognizes that, in their review of the 2019 draft PA and the 2021 draft PA, the CASAC generally agreed that it was reasonable to retain the primary 24-hour PM_{10} standard given the available scientific evidence, including retaining PM_{10} as the indicator. He concludes that the newly available evidence does not call into question the adequacy of the current primary PM_{10} standard, and retains that standard, without revision.

With respect to the secondary PM standards, this reconsideration focuses on visibility, climate, and materials effects.[4] The Administrator's final decision to not change the current secondary standards at this time has been informed by key aspects of the currently available welfare effects evidence as well as the conclusions contained in the 2019 ISA and ISA Supplement; quantitative analyses of visibility impairment; policy evaluations presented in the 2022 PA; advice from the CASAC; and public comments. Specifically, the welfare effects evidence available in this reconsideration is consistent with the evidence available in previous reviews and supports a causal relationship between PM and visibility, climate, and materials effects. With regard to visibility effects, the Administrator notes that he judges that the evidence supports a target level of protection of 27 dv. He further notes that the results of quantitative analyses of visibility impairment suggest that in areas that meet the current secondary 24-hour $PM_{2.5}$ standard that estimated light extinction in terms of a 3-year visibility metric would be at or well below the target level of protection. With regard to climate and materials effects, while the evidence has expanded since previous reviews, significant limitations and uncertainties remain in the evidence. While the evidence has expanded since previous reviews, the available scientific evidence remains insufficient to allow the Administrator to make a reasoned judgment about what specific standard(s) would be requisite to protect against known or anticipated adverse effects to public welfare from PM's effects on materials damage or climate.- In their review of the 2019 draft PA and the 2021 draft PA, the CASAC did not recommend revising the secondary PM standards. In considering the available evidence and quantitative information, with its inherent uncertainties and limitations, the Administrator judges that it is appropriate not to change the secondary PM standards at this time.

The final revisions to the primary annual $PM_{2.5}$ NAAQS trigger a process under which States (and Tribes, if they choose) make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the new or revised PM NAAQS. Those areas that do not meet the revised PM NAAQS will need to develop plans that demonstrate how they will meet the standards. As part of these plans, states have the opportunity to advance environmental justice, in this case for overburdened communities in areas with high PM concentrations above the NAAQS, by using the tools described in the current PM NAAQS implementation guidance (80 FR 58010, 58136, August 25, 2016). The EPA is not making changes to any of the current PM NAAQS implementation programs in this final rulemaking.

On other topics, the EPA is finalizing two sets of changes to the $PM_{2.5}$ sub-index of the Air Quality Index (AQI). First, the EPA is continuing to use the approach used in the revisions to the AQI in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100 and 150) based on the levels of the primary annual and 24-hour $PM_{2.5}$ standards. In so doing, the EPA is revising the AQI value of 50 to 9.0 μg/m³ and is retaining the AQI values of 100 and 150 at 35.4 μg/m³ and 55.4 μg/m³, respectively. Second, the EPA is revising the upper AQI breakpoints (200 and above), and replacing the linear-relationship approach used in 1999 (64 FR 42530, August 4, 1999) to set these breakpoints, with an approach that more fully considers the $PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that has become available in the last 20 years. The EPA is also revising the AQI values of 200, 300 and 500 to 125.4 μg/m³, 225.4 μg/m³, and 325.4 μg/m³, respectively. In addition, this final rule revises the daily reporting requirement from 5 days per week to 7 days per week, while also reformatting appendix G and providing clarifications.

With regard to monitoring-related activities, the EPA finalizes revisions to data calculations and ambient air monitoring requirements for PM to improve the usefulness and appropriateness of data used in regulatory decision making and to better characterize air quality in communities that are at increased risk of $PM_{2.5}$ exposure and health risk. These changes are found in 40 CFR part 50 (appendices K, L, and N), part 53, and part 58 with associated appendices (A, B, C, D, and E). These changes include addressing updates in data calculations, approval of reference and equivalent methods, updates in quality assurance statistical calculations to account for lower concentration measurements, updates to support improvements in PM methods, a revision to the $PM_{2.5}$ network design to account for at-risk populations, and updates to the Probe and Monitoring Path Siting Criteria for NAAQS pollutants.

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the Supreme Court in *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001), as discussed in section II.A of this document. As has traditionally been

[4] Consistent with the 2016 Integrated Review Plan (U.S. EPA, 2016), other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. Accordingly, the public welfare protection provided by the secondary PM standards against ecological effects such as those related to deposition of nitrogen- and sulfur-containing compounds in vulnerable ecosystems is being considered in that separate review. Thus, the Administrator's conclusion in this reconsideration of the 2020 final decision is focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials and hereafter ''welfare effects'' refers to those welfare effects.

done in NAAQS rulemaking, the EPA prepared a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative $PM_{2.5}$ standard levels. In NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 14094, 13563, and 12866. The RIA estimates the costs and monetized human health benefits of attaining the revised and two alternative annual $PM_{2.5}$ standard levels and one alternative 24-hour $PM_{2.5}$ standard level. Specifically, the RIA examines the revised annual standard level of 9.0 μg/m^3 in combination with the current 24-hour standard of 35 μg/m^3 (*i.e.,* 9.0/35 μg/m^3), as well as the following less and more stringent alternative standard levels: (1) An alternative annual standard level of 10.0 μg/m^3 in combination with the current 24-hour standard (*i.e.,* 10.0/35 μg/m^3), (2) an alternative annual standard level of 8.0 μg/m^3 in combination with the current 24-hour standard (*i.e.,* 8.0/35 μg/m^3), and (3) an alternative 24-hour standard level of 30 μg/m^3 in combination with an alternative annual standard level of 10 μg/m^3 (*i.e.,* 10.0/30 μg/m^3). The RIA presents estimates of the costs and benefits of applying illustrative national control strategies in 2032 after implementing existing and expected regulations and assessing emissions reductions to meet the current annual and 24-hour particulate matter NAAQS (12.0/35 μg/m^3).

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those pollutants ''emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare''; ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources''; and for which he ''plans to issue air quality criteria. . . .'' (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. . . .'' (42 U.S.C. 7408(a)(2)).

Section 109 [42 U.S.C. 7409] directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued [42 U.S.C. 7409(a)]. Section 109(b)(1) defines primary standards as ones ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [5] Under section 109(b)(2), a secondary standard must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [6]

In setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corporation* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute* v. *Costle,* 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1161–62; *Mississippi* v. *EPA,* 744 F.3d at 1353.

Section 109(d)(1) of the Act requires the review every five years of existing air quality criteria and, if appropriate, the revision of those criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to review every five years and, if appropriate, revise the NAAQS, based on the revised air quality criteria. Section 109(d)(1) also provides that the Administrator may review and revise criteria or promulgate new standards earlier or more frequently.

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of ''seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air

[5] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[6] Under CAA section 302(h) (42 U.S.C. 7602(h)), effects on welfare include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

pollution control agencies.'' Section 109(d)(2)(B) provides that the independent scientific review committee ''shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate. . . .'' Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board.

As previously noted, the Supreme Court has held that section 109(b) ''unambiguously bars cost considerations from the NAAQS-setting process.'' *Whitman* v. *Am. Trucking Associations,* 531 U.S. 457, 471 (2001). Accordingly, while some of these issues regarding which Congress has directed the CASAC to advise the Administrator are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established.

B. Related PM Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110, Part C, and Part D, Subparts 1 and 4 of the CAA, and related provisions and regulations, States are to submit, for the EPA's approval, State implementation plans (SIPs) that provide for the attainment and maintenance of the NAAQS for PM through control programs directed to sources of the pollutants involved. The States, in conjunction with the EPA, also administer the prevention of significant deterioration of air quality program that covers these pollutants (see 42 U.S.C. 7470–7479). In addition, Federal programs provide for or result in nationwide reductions in emissions of PM and its precursors under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for motor vehicles and nonroad engines and equipment; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emissions standards for hazardous pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. Review of the Air Quality Criteria and Standards for Particulate Matter

1. Reviews Completed in 1971 and 1987

The EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on the original Air Quality Criteria Document (AQCD) (DHEW, 1969).[7] The Federal reference method (FRM) specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 μm (referred to as total suspended particulates or TSP). The primary standards were set at 260 μg/m^3, 24-hour average, not to be exceeded more than once per year, and 75 μg/m^3, annual geometric mean. The secondary standards were set at 150 μg/m^3, 24-hour average, not to be exceeded more than once per year, and 60 μg/m^3, annual geometric mean.

In October 1979 (44 FR 56730, October 2, 1979), the EPA announced the first periodic review of the air quality criteria and NAAQS for PM. Revised primary and secondary standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In the 1987 decision, the EPA changed the indicator for particles from TSP to PM_{10}, in order to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of the respiratory tract (including the tracheobronchial and alveolar regions), referred to as thoracic particles.[8] The level of the 24-hour standards (primary and secondary) was set at 150 μg/m^3, and the form was one expected exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 μg/m^3, and the form was the annual arithmetic mean, averaged over three years.

2. Review Completed in 1997

In April 1994, the EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and in 1997 the EPA promulgated revisions to the NAAQS (62 FR 38652, July 18, 1997). In the 1997 decision, the EPA determined that the fine and coarse fractions of PM_{10} should be considered separately. This determination was based on evidence that serious health effects were associated with short- and long-term exposures to fine particles in areas that met the existing PM_{10} standards. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm). The new primary standards were as follows: (1) An annual standard with a level of 15.0 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors;[9] and (2) a 24-hour standard with a level of 65 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address the health effects of the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10–2.5}$, generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm), the EPA retained the primary annual PM_{10} standard and revised the form of the primary 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by setting them equal in all respects to the primary standards.

Following promulgation of the 1997 PM NAAQS, petitions for review were filed by several parties, addressing a broad range of issues. In May 1999, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the EPA's decision to establish fine particle standards and to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for coarse particles. *American Trucking Associations, Inc.* v. *EPA,* 175 F. 3d 1027 (D.C. Cir. 1999). Pursuant to the D.C. Circuit's decision, the EPA removed the vacated 1997 PM_{10} standards, and the pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The D.C. Circuit also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. *American Trucking Associations* v. *EPA,* 175 F. 3d at 1027.

[7] Prior to the review initiated in 2007 (see below), the AQCD provided the scientific foundation (*i.e.,* the air quality criteria) for the NAAQS. Beginning in that review, the Integrated Science Assessment (ISA) has replaced the AQCD.

[8] PM_{10} refers to particles with a nominal mean aerodynamic diameter less than or equal to 10 μm. More specifically, 10 μm is the aerodynamic diameter for which the efficiency of particle collection is 50 percent.

[9] The 1997 annual $PM_{2.5}$ standard was compared with measurements made at the community-oriented monitoring site recording the highest concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (*i.e.,* ''spatial averaging''). In the last review (completed in 2012) the EPA replaced the term ''community-oriented'' monitor with the term ''area-wide'' monitor. Area-wide monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro- or middle-scales that are representative of many such locations in the same core-based statistical area (CBSA) (78 FR 3236, January 15, 2013).

The D.C. Circuit also addressed more general issues related to the NAAQS, including issues related to the consideration of costs in setting NAAQS and the EPA's approach to establishing the levels of NAAQS. Regarding the cost issue, the court reaffirmed prior rulings holding that in setting NAAQS the EPA is ''not permitted to consider the cost of implementing those standards.'' *American Trucking Associations* v. *EPA,* 175 F. 3d at 1040–41. Regarding the levels of NAAQS, the court held that the EPA's approach to establishing the level of the standards in 1997 (*i.e.,* both for PM and for the ozone NAAQS promulgated on the same day) effected ''an unconstitutional delegation of legislative authority.'' *American Trucking Associations* v. *EPA,* 175 F. 3d at 1034–40. Although the court stated that ''the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable,'' it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants ''what EPA lacks is any determinate criterion for drawing lines'' to determine where the standards should be set.

The D.C. Circuit's holding on the cost and constitutional issues were appealed to the United States Supreme Court. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the cost and constitutional issues. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be ''requisite'' to protect public health with an adequate margin of safety sufficiently guided the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary.

The Supreme Court remanded the case to the D.C. Circuit for resolution of any remaining issues that had not been addressed in that court's earlier rulings. Id. at 475–76. In a March 2002 decision, the D.C. Circuit rejected all remaining challenges to the standards, holding that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Associations* v. *EPA,* 283 F. 3d 355, 369–72 (D.C. Cir. 2002).

3. Review Completed in 2006

In October 1997, the EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After the CASAC and public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the AQCD in October 2004 (U.S. EPA, 2004a). The EPA's Office of Air Quality Planning and Standards (OAQPS) finalized a Risk Assessment and Staff Paper in December 2005 (Abt Associates, 2005; U.S. EPA, 2005).[10] On December 20, 2005, the EPA announced its proposed decision to revise the NAAQS for PM and solicited public comment on a broad range of options (71 FR 2620, January 17, 2006). On September 21, 2006, the EPA announced its final decisions to revise the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the 24-hour $PM_{2.5}$ standards to 35 $\mu g/m^3$, retained the level of the annual $PM_{2.5}$ standards at 15.0 $\mu g/m^3$, and revised the form of the annual $PM_{2.5}$ standards by narrowing the constraints on the optional use of spatial averaging. With regard to the primary and secondary standards for PM_{10}, the EPA retained the 24-hour standards, with levels at 150 $\mu g/m^3$, and revoked the annual standards. The then-Administrator judged that the available evidence generally did not suggest a link between long-term exposure to existing ambient levels of coarse particles and health or welfare effects. In addition, a new reference method was added for the measurement of $PM_{10-2.5}$ in the ambient air in order to provide a basis for approving Federal Equivalent Methods (FEMs) and to promote the gathering of scientific data to support future reviews of the PM NAAQS.

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. On February 24, 2009, the D.C. Circuit issued its opinion in the case *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to the EPA because the Agency had failed to adequately explain why the standards provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations. *Id. at* 520–27. With regard to the standards for $PM_{10,}$ the court upheld the EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *Id.* at 533–38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *Id.* at 528–32. The EPA responded to the court's remands as part of the next review of the PM NAAQS, which was initiated in 2007 (discussed below).

4. Review Completed in 2012

In June 2007, the EPA initiated the fourth periodic review of the air quality criteria and the PM NAAQS by issuing a call for information (72 FR 35462, June 28, 2007). Based on the NAAQS review process, as revised in 2008 and again in 2009,[11] the EPA held science/policy issue workshops on the primary and secondary PM NAAQS (72 FR 34003, June 20, 2007; 72 FR 34005, June 20, 2007), and prepared and released the planning and assessment documents that comprise the review process (*i.e.,* Integrated Review Plan, (IRP; U.S. EPA, 2008), Integrated Science Assessment (ISA; U.S. EPA, 2009a), Risk and Exposure Assessment (REA) planning documents for health and welfare (U.S. EPA, 2009b, U.S. EPA, 2009c), a quantitative health risk assessment (U.S. EPA, 2010a) and an urban-focused visibility assessment (U.S. EPA, 2010b), and a Policy Assessment (PA; U.S. EPA, 2011). In June 2012, the EPA announced its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012).

In December 2012, the EPA announced its final decisions to revise the primary NAAQS for PM to provide increased protection of public health (78 FR 3086, January 15, 2013). With regard to primary standards for $PM_{2.5}$, the EPA revised the level of the annual $PM_{2.5}$ standard [12] to 12.0 $\mu g/m^3$ and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$. For the primary PM_{10} standard, the EPA retained the 24-hour standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (*i.e.,* $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA generally retained the 24-hour

[10] Prior to the review initiated in 2007, the Staff Paper presented the EPA staff's considerations and conclusions regarding the adequacy of existing NAAQS and, when appropriate, the potential alternative standards that could be supported by the evidence and information. More recent reviews present this information in the Policy Assessment.

[11] The history of the NAAQS review process, including revisions to the process, is discussed at *https://www.epa.gov/naaqs/historical-information-naaqs-review-process.*

[12] The EPA also eliminated the option for spatial averaging.

and annual $PM_{2.5}$ standards [13] and the 24-hour PM_{10} standard to address visibility and non-visibility welfare effects.

As with previous reviews, petitioners challenged the EPA's final rule. Petitioners argued that the EPA acted unreasonably in revising the level and form of the annual standard and in amending the monitoring network provisions. On judicial review, the revised standards and monitoring requirements were upheld in all respects. *NAM* v. *EPA,* 750 F.3d 921 (D.C. Cir. 2014).

5. Review Initiated in 2014

In December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the $PM_{2.5}$ and PM_{10} NAAQS and issued a call for information (79 FR 71764, December 3, 2014). On February 9 to 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). Workshop participants, including a wide range of external experts as well as the EPA staff representing a variety of areas of expertise (*e.g.,* epidemiology, human and animal toxicology, risk/exposure analysis, atmospheric science, visibility impairment, climate effects), were asked to highlight significant new and emerging PM research, and to make recommendations to the Agency regarding the design and scope of the review. This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA structured the review of the PM NAAQS and of the most meaningful new scientific information that would be available in the review to inform understanding of these issues.

The input received at the workshop guided the EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Panel and discussed on public teleconferences held in May 2016 (81 FR 13362, March 14, 2016) and August 2016 (81 FR 39043, June 15, 2016). Advice from the CASAC, supplemented by the Particulate Matter Panel, and input from the public were considered in developing the final IRP (U.S. EPA, 2016). The final IRP discusses the approaches to be taken in developing key scientific, technical, and policy documents in the review and the key policy-relevant issues that frame the EPA's consideration of whether the primary and/or secondary NAAQS for PM should be retained or revised.

In May 2018, the then-Administrator issued a memorandum announcing the Agency's intention to conduct the review of the PM NAAQS in such a manner as to ensure that any necessary revisions were finalized by December 2020 (Pruitt, 2018). Following this memo, on October 10, 2018, the then-Administrator additionally announced that the role of reviewing the key assessments developed as part of the ongoing review of the PM NAAQS (*i.e.,* drafts of the ISA and PA) would be performed by the seven-member chartered CASAC (*i.e.,* rather than the CASAC Particulate Matter Panel that reviewed the draft IRP).[14]

The EPA released the draft ISA in October 2018 (83 FR 53471, October 23, 2018). The draft ISA was reviewed by the chartered CASAC at a public meeting held in Arlington, VA in December 2018 (83 FR 55529, November 6, 2018) and was discussed on a public teleconference in March 2019 (84 FR 8523, March 8, 2019). The CASAC provided its advice on the draft ISA in a letter to the then-Administrator dated April 11, 2019 (Cox, 2019a). The EPA addressed these comments in the final ISA, which was released in December 2019 (U.S. EPA, 2019a).

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA was reviewed by the chartered CASAC and discussed in October 2019 at a public meeting held in Cary, NC. Public comments were received via a separate public teleconference (84 FR 51555, September 30, 2019). A public meeting to discuss the chartered CASAC letter and response to charge questions on the draft PA was held in Cary, NC, in October 2019 (84 FR 51555, September 30, 2019), and the CASAC provided its advice on the draft PA, including its advice on the current primary and secondary PM standards, in a letter to the then-Administrator dated December 16, 2019 (Cox, 2019b). With regard to the primary standards, the CASAC recommended retaining the current 24-hour $PM_{2.5}$ and PM_{10} standards but did not reach consensus on the adequacy of the current annual $PM_{2.5}$ standard. Some CASAC members expressed support for retaining the current primary annual $PM_{2.5}$ standard while other members expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p. 1 of letter). These views are described in greater detail in the letter to the then-Administrator (Cox, 2019b) and in the notice of final rulemaking (85 FR 82706–82707, December 18, 2020), as well as below. With regard to the secondary standards, the CASAC recommended retaining the current standards. In response to the CASAC's comments, the 2020 final PA incorporated a number of changes (Cox, 2019b, U.S. EPA, 2020b), as described in detail in section I.C.5 of the 2020 proposal document (85 FR 24100, April 30, 2020).

a. 2020 Proposed and Final Actions

On April 14, 2020, the EPA proposed to retain all of the primary and secondary PM standards, without revision. These proposed decisions were published in the **Federal Register** on April 30, 2020 (85 FR 24094, April 30, 2020). The EPA's final decision on the PM NAAQS was published in the **Federal Register** on December 18, 2020 (85 FR 82684, December 18, 2020). In the 2020 rulemaking, the EPA retained the primary and secondary $PM_{2.5}$ and PM_{10} standards, without revision. The then-Administrator's rationale for his decisions is described in more detail in section II, III, and V below, and is briefly summarized here.

In reaching his final decision to retain the primary annual and 24-hour $PM_{2.5}$ standards, the then-Administrator considered the available scientific evidence, quantitative information, CASAC advice, and public comments in his supporting rationale in the 2020 final action (85 FR 82714, December 18, 2020). In so doing, he concluded that the available controlled human exposure studies did not provide support for additional public health protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the current primary annual and 24-hour $PM_{2.5}$ standards. He also noted that the available epidemiologic studies did not indicate that associations in those studies are strongly influenced by exposures to peak concentrations in the air quality distribution and thus did not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations. Accordingly, and taking into account consensus CASAC advice to retain the current primary 24-hour $PM_{2.5}$ standard, the then-Administrator concluded the primary 24-hour $PM_{2.5}$ standard should be retained.

With respect to the annual $PM_{2.5}$ standard, the then-Administrator recognized that important uncertainties and limitations that were present in epidemiologic studies in previous

[13] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard.

[14] Announcement available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2015-0072-0223.*

reviews remained in the evidence assessed in the 2019 ISA. In considering the epidemiologic evidence, the then-Administrator noted that: (1) The reported mean concentration in the majority of the key U.S. epidemiologic studies using ground-based monitoring data are above the level of the current annual standard; (2) the mean of the reported study means (or medians) (*i.e.,* 13.5 $\mu g/m^3$) is above the level of the current primary annual $PM_{2.5}$ standard of 12 $\mu g/m^3$; (3) air quality analyses show the study means to be lower than their corresponding design by 10–20%; and (4) that these analyses must be considered in light of uncertainties inherent in the epidemiologic evidence. The then-Administrator further considered other available information, including the risk assessment, accountability studies, and controlled human exposure studies, and found that, in considering all of the evidence together along with advice from the CASAC, the suite of primary $PM_{2.5}$ standards were requisite to protect public health with an adequate margin of safety, and should be retained, without revision.

With regard to the primary PM_{10} standard, the then-Administrator noted that the expanded body of evidence has broadened the range of effects that have been linked with $PM_{10–2.5}$ exposures. In light of that information, as well as continued uncertainties in the evidence and advice from the CASAC to retain the standard, the then-Administrator judged it appropriate to retain the primary PM_{10} standard to provide the requisite degree of public health protection against $PM_{10–2.5}$ exposures, regardless of location, source of origin, or particle composition (85 FR 82725, December 18, 2020).

With regard to the secondary PM standards, the then-Administrator concluded that there was insufficient information available to establish any distinct secondary PM standards to address climate and materials effects of PM. For visibility effects, he found that in the absence of a monitoring network for direct measurement of light extinction, a calculated light extinction indicator that utilizes the IMPROVE algorithms continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment. He further found that a visibility index with a 24-hour averaging time was reasonable based on its stability and suitability for representing subdaily periods, and a form based on the 3-year average of annual 90th percentile values was reasonable based on its stability and that it represents the median of the 20 percent worst visibility days which are targeted under the Regional Haze program. With regard to the level of a visibility index, the then-Administrator judged it appropriate to establish a target level of protection of 30 dv, reflecting the upper end of the range of visibility impairment judged to be acceptable by at least 50% of study participants in the available public preference studies, taking into consideration the variability, limitations and uncertainties of the public preference studies. The then-Administrator judged that the secondary 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$ would provide at least the target level of protection for visual air quality of 30 dv which he judged appropriate. Accordingly, taking into consideration the advice of the CASAC to retain the current secondary PM standards, the then-Administrator found the current secondary standards provide the requisite degree of protection and that they should be retained (85 FR 82742, December 18, 2020).

Following publication of the 2020 final action, several parties filed petitions for review and petitions for reconsideration of the EPA's final decision. The petitions for review were filed in the D.C. Circuit and the Court consolidated the cases.[15] Following EPA's decision to reconsider the 2020 final decision, the Court ordered the consolidated cases to be held in abeyance.

b. Reconsideration of the 2020 PM NAAQS Final Action

Executive Order 13990 directed review of certain agency actions (86 FR 7037, January 25, 2021).[16] An accompanying fact sheet provided a non-exclusive list of agency actions that agency heads should review in accordance with that order, including the 2020 Particulate Matter NAAQS Decision.[17]

On June 10, 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act.[18] The Administrator reached this decision in part based on the fact that the EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary annual $PM_{2.5}$ standard and supported revising the level to below the current level of 12.0 $\mu g/m^3$ while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020b). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information supported retaining the primary PM_{10} standard and secondary PM standards without revision (U.S. EPA, 2020b).

The EPA staff conclusions detailed in the 2020 PA in combination with the CASAC advice that informed the Administrator's decisions regarding the 2020 final action, studies highlighted by public comments on the 2020 proposal, and the numerous studies published since the literature cutoff date of the 2019 ISA all informed the scope of the reconsideration.

In its review of the 2019 draft PA, some members of the CASAC had recommended that greater attention should be given to accountability studies and epidemiologic studies that employ alternative methods for confounder control (also referred to as causal inference or causal modeling studies) in order to ''more fully account for effects of confounding, measurement and estimation errors, model uncertainty, and heterogeneity'' in epidemiologic studies (Cox, 2019b, p. 8 of consensus responses). In addition, public commenters submitted a number of recent studies published after the literature cutoff date for the 2019 ISA that would have been considered within the scope of the 2019 ISA. While the EPA provisionally considered these studies in responding to public comments,[19] it was determined that, at the time of the 2020 final action, these studies were generally consistent with the evidence assessed in the 2019 ISA (85 FR 82690, December 18, 2020; U.S. EPA, 2020a). As such, and consistent with previous NAAQS reviews, the EPA concluded that the new studies did not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria, and therefore, reopening of the air quality criteria was not warranted (85 FR 82691, December 18, 2020). However, at that time, the EPA

[15] See *California* v. *EPA,* (D.C. Cir., No. 21–2014 consolidated with Nos. 21–1027, 21–1054).

[16] See *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/.*

[17] See *https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/.*

[18] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged.*

[19] The list of provisionally considered studies is included in Appendix A to the 2020 Response to Comments document (U.S. EPA, 2020a).

recognized that its ''provisional consideration of these studies did not and could not provide the kind of in-depth critical review'' (85 FR 82690, December 18, 2020) that studies undergo in the development of an ISA.

In preparing to reconsider the 2020 final decision for the PM NAAQS, the Agency revisited the need to reopen the air quality criteria, given the amount of time that had passed since the literature cutoff date of the 2019 ISA (*i.e.,* approximately January 2018) and the volume of literature that had become available, including those studies provisionally considered in responding to comments in 2020. In so doing, the EPA preliminarily concluded that at least some of these studies were likely to be relevant to its reconsideration of the air quality criteria and the PM NAAQS and that, in considering public comments on any proposed decisions for the reconsideration, these studies were likely to be raised by public commenters and would potentially warrant a reopening of the air quality criteria. For example, on February 16, 2021, the EPA received two petitions to reconsider the PM NAAQS. One petition objected to the EPA's provisional consideration of studies submitted in public comments on the 2020 proposal and suggested that the provisional consideration was inadequate because the studies could be important in determining whether the existing standards are adequately protective. See, Petition for Reconsideration of National Ambient Air Quality Standards for Particulate Matter, submitted by American Lung Association, et al, dated Feb. 16, 2020. The other petition identified a number of new studies, including one epidemiologic study that was published after the provisional consideration was completed that could further inform the concern expressed by the CASAC that associations reported in epidemiologic studies do not adequately account for ''uncontrolled confounding and other potential sources of error and bias.'' See Petition for Reconsideration of ''Review of the National Ambient Air Quality Standards for Particulate Matter,'' submitted by the State of California, dated Feb. 16, 2020. This was also an uncertainty noted by the then-Administrator in the 2020 decision, who also recognized ''that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study.'' Thus, the Agency concluded it was appropriate to reconsider not only the standards but also the air quality criteria, in light of public comments during the 2020 PM NAAQS proposal and recent studies published since the cutoff date of the 2019 ISA, as reflected in petitions. In deciding to reopen the air quality criteria, the Agency concluded it was reasonable to focus on studies that were most likely to inform decisions on the appropriate standard, but not to reassess areas which, based on the assessment of available science published since the cutoff date of the 2019 ISA and through 2021, were judged unlikely to have new information that would be useful for the Administrator's decision making. The Agency accordingly announced that, in support of the reconsideration, it would develop a supplement to the 2019 ISA and a revised PA.

The EPA also explained that the draft ISA Supplement and draft PA would be reviewed at a public meeting by the CASAC, and the public would have opportunities to comment on these documents during the CASAC review process, as well as to provide input during the rulemaking through the public comment process and public hearings on the proposed rulemaking.

On March 31, 2021, the Administrator announced his decision to reestablish the membership of the CASAC to ''ensure the agency received the best possible scientific insight to support our work to protect human health and the environment.'' [20] Consistent with this memorandum, a call for nominations of candidates to the EPA's chartered CASAC was published in the **Federal Register** (86 FR 17146, April 1, 2021). On June 17, 2021, the Administrator announced his selection of the seven members to serve on the chartered CASAC.[21] [22] Additionally, a call for nominations of candidates to a PM-specific panel was published in the **Federal Register** (86 FR 33703, June 25, 2021). The members of the PM CASAC panel were announced on August 30, 2021.[23]

The draft ISA Supplement was released in September 2021 (U.S. EPA, 2021a; 86 FR 54186, September 30, 2021), and included a discussion of the rationale and scope of the Supplement. As explained therein, the ISA Supplement focuses on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA. In selecting the health effects to evaluate within the ISA Supplement, the EPA focused on health effects for which the evidence supported a ''causal relationship'' because those were the health effects that were most useful in informing conclusions in the 2020 PA (U.S. EPA, 2022a, section 1.2.1).[24] Consistent with the rationale for the focus on certain health effects, in selecting the non-ecological welfare effects to evaluate within the ISA Supplement, the EPA focused on the non-ecological welfare effects for which the evidence supported a ''causal relationship'' and for which quantitative analyses could be supported by the evidence because those were the welfare effects that were most useful in informing conclusions in the 2020 PA.[25] Specifically, for non-ecological welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement also considers recent health effects evidence that addresses key scientific topics where the literature has evolved since the 2020 review was completed,

[20] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/administrator-regan-directs-epa-reset-critical-science-focused-federal-advisory.*

[21] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-announces-selections-charter-members-clean-air-scientific-advisory-committee.*

[22] The list of members of the chartered CASAC and their biosketches are available at: *https://casac.epa.gov/ords/sab/r/sab_apex/casac/mems?p14_committeeon=2021%20CASAC%20PM%20Panel&session=17433386035954.*

[23] The list of members of the PM CASAC panel and their biosketches are available at: *https://casac.epa.gov/ords/sab/f?p=105:14:9979229564047:::14:P14_COMMITTEEON:2021%20CASAC%20PM%20Panel.*

[24] As described in section 1.2.1 of the ISA Supplement: ''In considering the public health protection provided by the current primary $PM_{2.5}$ standards, and the protection that could be provided by alternatives, [the U.S. EPA, within the 2020 PM PA] emphasized health outcomes for which the ISA determined that the evidence supports either a '*causal*' or a '*likely to be causal*' relationship with $PM_{2.5}$ exposures'' (U.S. EPA, 2020b). Although the 2020 PA initially focused on this broader set of evidence, the basis of the discussion on potential alternative standards primarily focused on health effect categories where the 2019 PM ISA concluded a '*causal relationship*' (*i.e.,* short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality) as reflected in Figures 3–7 and 3–8 of the 2020 PA (U.S. EPA, 2020b).''

[25] As described in section 1.2.1 of the ISA Supplement: ''The 2019 PM ISA concluded a '*causal relationship*' for each of the welfare effects categories evaluated (*i.e.,* visibility, climate effects and materials effects). While the 2020 PA considered the broader set of evidence for these effects, for climate effects and material effects, it concluded that there remained 'substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects' (U.S. EPA, 2020b).''

specifically since the literature cutoff date for the 2019 ISA.[26]

Building on the rationale presented in section 1.2.1, the ISA Supplement considers peer-reviewed studies published from approximately January 2018 through March 2021 that meet the following criteria:

- Health Effects
  - U.S. and Canadian epidemiologic studies for health effect categories where the 2019 ISA concluded a ''*causal relationship*'' (*i.e.,* short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality).
  - U.S. and Canadian epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses (*i.e.,* examined the effect of a policy on reducing $PM_{2.5}$ concentrations).
- Welfare Effects
  - U.S. and Canadian studies that provide new information on public preferences for visibility impairment and/or developed methodologies or conducted quantitative analyses of light extinction.
- Key Scientific Topics
  - Experimental studies (*i.e.,* controlled human exposure and animal toxicological) conducted at near-ambient $PM_{2.5}$ concentrations experienced in the U.S.
  - U.S.- and Canadian-based epidemiologic studies that examined the relationship between $PM_{2.5}$ exposures and severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) infection and coronavirus disease 2019 (COVID–19) death.
  - At-Risk Populations.
  - U.S.- and Canadian-based epidemiologic or exposure studies examining potential disparities in either $PM_{2.5}$ exposures or the risk of health effects by race/ethnicity or socioeconomic status (SES).

Given the narrow scope of the ISA Supplement, it is important to recognize that the evaluation does not encompass the full multidisciplinary evaluation presented within the 2019 ISA that would result in weight-of-evidence conclusions on causality (*i.e.,* causality determinations). The ISA Supplement critically evaluates and provides key study-specific information for those recent studies deemed to be of greatest significance for informing preliminary conclusions on the PM NAAQS in the context of the body of evidence and scientific conclusions presented in the 2019 ISA.

In developing a revised PA to support the reconsideration, the EPA considered the available scientific evidence, including the evidence presented in the 2019 ISA and ISA Supplement. The 2022 PA considered the quantitative and technical information presented in the 2020 PA, in addition to new and updated analyses conducted since the 2020 final decision. For those health and welfare effects for which the ISA Supplement evaluated recently available studies (*i.e.,* $PM_{2.5}$-related health effects and visibility effects), new updated quantitative analyses were conducted as a part of the development of the 2022 PA. The newly available scientific and technical information presented in the 2022 PA were considered in reaching conclusions regarding the adequacy of the current standards and any potential alternative standards. For those health and welfare effects for which newly available scientific and technical information were not evaluated (*i.e.,* $PM_{10–2.5}$-related health effects and non-visibility welfare effects), the conclusions presented in the 2022 PA rely heavily on the information that supported the conclusions in the 2020 PA.

The CASAC PM panel met at a virtual public meeting in November 2021 to review the draft ISA Supplement (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022, and during this meeting the chartered CASAC considered the CASAC PM panel's draft letter to the Administrator on the draft ISA Supplement (87 FR 958, January 7, 2022).

The chartered CASAC provided its advice on the draft ISA Supplement in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022b). In its review of the draft ISA Supplement, the CASAC noted that they found ''the Draft ISA Supplement to be a well-written, comprehensive evaluation of the new scientific information published since the 2019 PM ISA'' (Sheppard, 2022b, p. 2 of letter). Furthermore, the CASAC stated that ''the final Integrated Science Assessment (ISA) Supplement . . . deserve[s] the Administrator's full consideration and [is] adequate for rulemaking'' (Sheppard, 2022b, p. 2 of letter). The CASAC generally endorsed EPA's decisions regarding the limited scope of the draft ISA Supplement, stating that ''this limitation [on scope] is appropriate for the targeted purpose of the Draft ISA Supplement'' although the CASAC noted it would not be appropriate for ISAs generally, and recommended that the EPA provide additional acknowledgment and explanation for the limited scope (Sheppard, 2022b, p. 2 of letter; see also pp. 2–3 of consensus responses). The EPA specifically noted in the final ISA Supplement, which was released in May 2022 (U.S. EPA, 2022a; hereafter referred to as the ISA Supplement throughout this document) that the ''targeted approach to developing the Supplement to the 2019 PM ISA for the purpose of reconsidering the 2020 PM NAAQS decision does not reflect a change to EPA's approach for developing ISAs for NAAQS reviews.'' Thus, the evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 PM NAAQS final decision.

The draft PA was released in October 2021 (86 FR 56263, October 8, 2021). The CASAC PM panel met at a virtual public meeting in December 2021 to review the draft PA (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022 and March 2022, and during this meeting the chartered CASAC considered the CASAC PM panel's draft letter to the Administrator on the draft PA (87 FR 958, January 7, 2022). The chartered CASAC provided its advice on the draft PA in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022a). The EPA took steps to address these comments in revising and finalizing the PA. The 2022 PA considers the scientific evidence presented in the 2019 ISA and ISA Supplement and considers the quantitative and technical information presented in the 2020 PA, along with updated and newly available analyses since the completion of the 2020 review. For those health and welfare effects for which the ISA Supplement evaluated recently available evidence and for which updated quantitative analyses were supported (*i.e.,* $PM_{2.5}$-related health effects and visibility effects), the 2022 PA includes consideration of this newly available scientific and technical information in reaching preliminary conclusions. For those health and welfare effects for which newly available scientific and technical

[26] These key scientific topics include experimental studies conducted at near-ambient concentrations, epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses, studies that assess the relationship between $PM_{2.5}$ exposure and severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) infection and coronavirus disease 2019 (COVID–19) death; and in accordance with recent EPA goals on addressing environmental justice, studies that examine disparities in $PM_{2.5}$ exposure and the risk of health effects by race/ethnicity or socioeconomic status (SES) (U.S. EPA, 2022a, section 1.2.1).

information were not evaluated (*i.e.,* $PM_{10–2.5}$-related health effects and non-visibility effects), the conclusions presented in the 2022 PA rely heavily on the information that supported the conclusions in the 2020 PA. The final PA was released in May 2022 (U.S. EPA, 2022b; hereafter referred to as the 2022 PA throughout this document).

Drawing from his consideration of the scientific evidence assessed in the 2019 ISA and ISA Supplement and the analyses in the 2022 PA, including the uncertainties in the evidence and analyses, and from his consideration of advice from the CASAC, on January 5, 2023, the Administrator proposed to revise the level of the primary annual $PM_{2.5}$ standard and to retain the primary 24-hour $PM_{2.5}$ standard, the primary 24-hour PM_{10} standard, and the secondary PM standards. These proposed decisions were published in the **Federal Register** on January 27, 2023 (88 FR 5558, January 27, 2023). The EPA held a multi-day virtual public hearing on February 21–23, 2023 (88 FR 6215, January 31, 2023). In total, the EPA received nearly 700,000 comments on the proposal from members of the public by the close of the public comment period on March 28, 2023. Major issues raised in the public comments are discussed throughout the preamble of this final action. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments'' document), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072).

As in prior reviews, the EPA is basing its decision in this reconsideration on studies and related information in the air quality criteria, which have undergone CASAC and public review. These studies assessed in the 2019 ISA [27] and ISA Supplement [28] and the 2022 PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. Decisions on the NAAQS should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily mandated independent scientific advisory committee, as well as the public review that accompanies this process. It is for this reason that the EPA preliminarily concluded that the scientific evidence available since the completion of the 2019 ISA, including those raised in public comments on the proposal in 2020, warranted a partial reopening of the air quality criteria and prepared an ISA Supplement to enable the EPA, the CASAC, and the public to consider them further. Some commenters have referred to and discussed additional individual scientific studies on the health effects of PM that were not included in the 2019 ISA or ISA Supplement (''new studies'') and that have not gone through this comprehensive review process. In considering and responding to comments for which such ''new'' studies were cited in support, the EPA has provisionally considered the cited studies in the context of the findings of the 2019 ISA and ISA Supplement. The EPA's provisional consideration of these studies did not and could not provide the kind of in-depth critical review described above, but rather was focused on determining whether they warranted further reopening the review of the air quality criteria to enable the EPA, the CASAC, and the public to consider them further.

This approach, and the decision to rely on the studies and related information in the air quality criteria, which have undergone CASAC and public review, is consistent with the EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and the EPA has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 6114, 61148 (October 17, 2006, final decision on review of NAAQS for particulate matter) for a detailed discussion of this issue and the EPA's past practice.

As discussed in the EPA's 1993 decision not to review the O_3 NAAQS, ''new'' studies may sometimes be of such significance that it is appropriate to delay a decision in a NAAQS review and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR 13013–13014, March 9, 1993). In the present case, the EPA decided to partially reopen the air quality criteria and prepared an ISA Supplement as a part of the reconsideration to facilitate evaluation of these studies by the EPA, the CASAC, and the public. The narrow scope of the ISA Supplement is supported by EPA's provisional consideration of ''new'' studies submitted in response to public comments on the 2020 proposal which concluded that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria. Therefore, a full reopening of the air quality criteria was not warranted to assess the health and welfare effects of PM for purposes of the review.

Accordingly, the EPA is basing the final decisions in this reconsideration on the studies and related information included in the PM air quality criteria (including the 2019 PM ISA and ISA Supplement) that have undergone rigorous review by the EPA, the CASAC, and the public. The EPA will consider these ''new'' studies for inclusion in the air quality criteria for the next PM NAAQS review, which the EPA expects to begin soon after the conclusion of this reconsideration and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, the CASAC, and the public.

D. Air Quality Information

This section provides a summary of basic information related to PM ambient air quality. It summarizes information on the distribution of particle size in ambient air (section I.D.1), sources and emissions contributing to PM in the ambient air (section I.D.2), monitoring ambient PM in the U.S. (section I.D.3), ambient PM concentrations and trends in the U.S. (I.D.4), characterizing ambient $PM_{2.5}$ concentrations for exposure (section I.D.5), and background PM (section I.D.6). Additional detail on PM air quality can be found in Chapter 2 of the 2022 PA (U.S. EPA, 2022b).

1. Distribution of Particle Size in Ambient Air

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles (U.S. EPA, 2019a, section 2.2) and distinct health and welfare effects have been linked with exposures to particles of different sizes. Particles in the atmosphere range in size from less than 0.01 to more than 10 μm

[27] In addition to the 2020 review's opening ''call for information'' (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES–2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

[28] As described above, the ISA Supplement represents an evaluation of recent studies that are of greatest policy relevance and utility to the reconsideration of the 2020 final decision on the PM NAAQS (U.S. EPA, 2022a).

in diameter (U.S. EPA, 2019a, section 2.2). The EPA defines $PM_{2.5}$, also referred to as fine particles, as particles with aerodynamic diameters generally less than or equal to 2.5 μm. The size range for $PM_{10–2.5}$, also called coarse or thoracic coarse particles, includes those particles with aerodynamic diameters generally greater than 2.5 μm and less than or equal to 10 μm. PM_{10}, which is comprised of both fine and coarse fractions, includes those particles with aerodynamic diameters generally less than or equal to 10 μm. In addition, ultrafine particles (UFP) are often defined as particles with a diameter of less than 0.1 μm based on physical size, thermal diffusivity or electrical mobility (U.S. EPA, 2019a, section 2.2). Atmospheric lifetimes are generally longest for $PM_{2.5}$, which often remains in the atmosphere for days to weeks (U.S. EPA, 2019a, Table 2–1) before being removed by wet or dry deposition, while atmospheric lifetimes for UFP and $PM_{10–2.5}$ are shorter and are generally removed from the atmosphere within hours, through wet or dry deposition (U.S. EPA, 2019a, Table 2–1; U.S. EPA, 2022b, section 2.1).

2. Sources and Emissions Contributing to PM in the Ambient Air

PM is composed of both primary (directly emitted particles) and secondary particles. Primary PM is derived from direct particle emissions from specific PM sources while secondary PM originates from gas-phase precursor chemical compounds present in the atmosphere that have participated in new particle formation or condensed onto existing particles (U.S. EPA, 2019a, section 2.3). As discussed further in the 2019 ISA (U.S. EPA, 2019a, section 2.3.2.1), secondary PM is formed in the atmosphere by photochemical oxidation reactions of both inorganic and organic gas-phase precursors. Precursor gases include sulfur dioxide (SO_2), nitrogen oxides (NO_X), and volatile organic compounds (VOC) (U.S. EPA, 2019a, section 2.3.2.1). Ammonia also plays an important role in the formation of nitrate PM by neutralizing sulfuric acid and nitric acid. Sources and emissions of PM are discussed in more detail the 2022 PA (U.S. EPA, 2022b, section 2.1.1). Briefly, anthropogenic sources of PM include both stationary (*e.g.,* fuel combustion for electricity production and other purposes, industrial processes, agricultural activities) and mobile (*e.g.,* diesel- and gasoline-powered highway vehicles and other engine-driven sources) sources. Natural sources of PM include dust from the wind erosion of natural surfaces, sea salt, wildfires, primary biological aerosol particles (PBAP) such as bacteria and pollen, oxidation of biogenic hydrocarbons, such as isoprene and terpenes to produce secondary organic aerosol (SOA), and geogenic sources, such as sulfate formed from volcanic production of SO_2. Wildland fire, which encompass both wildfire and prescribed fire, accounts for 44% of emissions of primary $PM_{2.5}$ emissions (U.S. EPA, 2021b). Emissions from wildfire comprises 29% of primary $PM_{2.5}$ emissions.

In recent years, the frequency and magnitude of wildfires have increased (U.S. EPA, 2019a). The magnitude of the public health impact of wildfires is substantial both because of the increase in $PM_{2.5}$ concentrations as well as the duration of the wildfire smoke season, which is considered to range from May to November. Wildfire can make a large contribution to air pollution (including $PM_{2.5}$), and wildfire events can threaten public safety and life. The impacts of wildfire events can be mitigated through management of wildland vegetation, including through prescribed fire. Prescribed fire (and some wildfires) can mimic the natural processes necessary to maintain fire-dependent ecosystems, minimizing catastrophic wildfires and the risks they pose to safety, property and air quality (see, *e.g.,* 81 FR 58010, 58038, August 24, 2016). The EPA views the strategic use of prescribed fire as an important tool for reducing wildfire risk and the severity of wildfires and wildfire smoke (88 FR, 54118, 54126, August 9, 2023).[29] As noted in the PM NAAQS proposal, agencies have efforts in place to reduce the frequency and severity of human-caused wildfires (88 FR 5570, January 27, 2023).

Wildfire events produce high PM emissions that may impact the PM concentrations in ambient air to the extent that the concentrations result in an exceedance or violation which may affect the design value in a given area. The EPA's Exceptional Events Rule (81 FR 68216, October 3, 2016) describes the process by which air agencies may request to exclude 'event-influenced' data caused by exceptional events, which can include wildfires and prescribed fires on wildland. The EPA has issued guidance specifically addressing exceptional events demonstrations for both wildfires and prescribed fires on wildland. These documents are available on EPA's Exceptional Events Program website.[30] The EPA will develop fire-related exceptional events implementation tools, including updates as needed to existing guidance to facilitate more efficient processing of $PM_{2.5}$-related exceptional events demonstrations for both the 24-hour and annual standards.

3. Monitoring of Ambient PM

To promote uniform application of the air quality standards set forth under the CAA and to achieve the degree of public health and welfare protection intended for the NAAQS, the EPA establishes PM Federal Reference Methods (FRMs) for both PM_{10} and $PM_{2.5}$ in appendices J and L to 40 CFR part 50, both of which were amended following the 2006 and 2012 PM NAAQS reviews. The current PM monitoring network relies on FRMs and automated continuous Federal Equivalent Methods (FEMs) approved pursuant to 40 CFR part 53, in part to support changes necessary for implementation of the revised PM standards. Additionally, 40 CFR part 58, appendices A through E, detail the requirements to measure ambient air quality and report ambient air quality data and related information. More information on PM ambient monitoring networks is available in section 2.2 of the 2022 PA (U.S. EPA, 2022b).

The $PM_{2.5}$ monitoring program is one of the major ambient air monitoring programs with a robust, nationally consistent network of ambient air monitoring sites providing mass and/or chemical speciation measurements. 40 CFR part 58, appendix D, section 4.7 provides the applicable $PM_{2.5}$ network design criteria. For most urban locations, $PM_{2.5}$ monitors are sited at the neighborhood scale,[31] where $PM_{2.5}$ concentrations are reasonably homogeneous throughout an entire urban sub-region. In each CBSA with a monitoring requirement, at least one $PM_{2.5}$ monitoring station representing

[29] See also: *https://www.usda.gov/sites/default/files/documents/usda-epa-doi-cdc-mou.pdf.*

[30] See: *https://www.epa.gov/air-quality-analysis/final-2016-exceptional-events-rule-supporting-guidance-documents-updated-faqs.*

[31] For $PM_{2.5}$, neighborhood scale is defined at 40 CFR part 58, appendix D, 4.7.1(c)(3) as follows: Measurements in this category would represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the $PM_{2.5}$ exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. $PM_{2.5}$ sites of this kind provide good information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for periods comparable to those specified in the NAAQS. In general, most $PM_{2.5}$ monitoring in urban areas should have this scale.

area-wide air quality is sited in an area of expected maximum concentration.[32] By ensuring the area of expected maximum concentration in a CBSA has a site compared to both the annual and 24-hour NAAQS, all other similar locations are thus protected. Sites that represent relatively unique microscale, localized hot-spot, or unique middle scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.

Under 40 CFR part 50, appendix L, and 40 CFR part 53, and 40 CFR part 58 appendix D there are three main methods components of the $PM_{2.5}$ monitoring program: filter-based FRMs measuring $PM_{2.5}$ mass, FEMs measuring $PM_{2.5}$ mass, and other samplers used to collect the aerosol used in subsequent laboratory analysis for measuring $PM_{2.5}$ chemical speciation. The FRMs are primarily used for comparison to the NAAQS, but also serve other important purposes, such as developing trends and evaluating the performance of FEMs. $PM_{2.5}$ FEMs are typically continuous methods used to support forecasting and reporting of the Air Quality Index (AQI) but are also used for comparison to the NAAQS. Samplers that are part of the Chemical Speciation Network (CSN) and Interagency Monitoring of Protected Visual Environments (IMPROVE) network are used to provide chemical composition of the aerosol and serve a variety of objectives. More detail on of each of these components of the $PM_{2.5}$ monitoring program and of recent changes to $PM_{2.5}$ monitoring requirements are described in detail in the 2022 PA (U.S. EPA, 2022b, section 2.2.3).

4. Ambient Concentrations and Trends

This section summarizes available information on recent ambient PM concentrations in the U.S. and on trends in PM air quality. Sections I.D.4.a and I.D.4.b summarize information on $PM_{2.5}$ mass and components, respectively. Section I.D.4.c summarizes information on PM_{10}. Sections I.D.4.d and I.D.4.e summarize the more limited information on $PM_{10-2.5}$ and UFP, respectively. Additional detail on PM air quality and trends can be found in the 2022 PA (U.S. EPA, 2022b, section 2.3).

a. $PM_{2.5}$ mass

At monitoring sites in the U.S., annual $PM_{2.5}$ concentrations from 2017 to 2019 averaged 8.0 μg/m³ (with the 10th and 90th percentiles at 5.9 and 10.0 μg/m³, respectively) and the 98th percentiles of 24-hour concentrations averaged 21.3 μg/m³ (with the 10th and 90th percentiles at 14.0 and 29.7 μg/m³, respectively) (U.S. EPA, 2022b, section 2.3.2.1). The highest ambient $PM_{2.5}$ concentrations occur in the western U.S., particularly in California and the Pacific Northwest (U.S. EPA, 2022b, Figure 2–15). Much of the eastern U.S. has lower ambient concentrations, with annual average concentrations generally at or below 12.0 μg/m³ and 98th percentiles of 24-hour concentrations generally at or below 30 μg/m³ (U.S. EPA, 2022b, section 2.3.2.1).

Recent ambient $PM_{2.5}$ concentrations reflect the substantial reductions that have occurred across much of the U.S. (U.S. EPA, 2022b, section 2.3.2.1). From 2000 to 2019, national annual average $PM_{2.5}$ concentrations declined from 13.5 μg/m³ to 7.6 μg/m³, a 43% decrease (U.S. EPA, 2022b, section 2.3.2.1).[33] These declines have occurred at urban and rural monitoring sites, although urban $PM_{2.5}$ concentrations remain consistently higher than those in rural areas (Chan et al., 2018) due to the impact of local sources in urban areas. Analyses at individual monitoring sites indicate that declines in ambient $PM_{2.5}$ concentrations have been most consistent across the eastern U.S. and in parts of coastal California, where both annual average and 98th percentiles of 24-hour concentrations declined significantly (U.S. EPA, 2022b, section 2.3.2.1). In contrast, trends in ambient $PM_{2.5}$ concentrations have been less consistent over much of the western U.S., with no significant changes since 2000 observed at some sites in the Pacific Northwest, the northern Rockies and plains, and the Southwest, particularly for 98th percentiles of 24-hour concentrations (U.S. EPA, 2022b, section 2.3.2.1). As noted below, some sites in the northwestern U.S. and California, where wildfire have been relatively common in recent years, have experienced high concentrations over shorter periods (*i.e.,* 2-hour averages).

The recent deployment of $PM_{2.5}$ monitors near major roads in large urban areas provides information on $PM_{2.5}$ concentrations near an important emissions source. For 2016–2018, Gantt et al. (2021) reported that 52% and 24% of the time near-road sites reported the highest annual and 24-hour $PM_{2.5}$ design value [34] in the CBSA, respectively. Of the CBSAs with the highest annual design values at near-road sites reported by Gantt et al. (2021), those design values were, on average, 0.8 μg/m³ higher than at the highest measuring non-near-road sites (range is 0.1 to 2.1 μg/m³ higher at near-road sites). Although most near-road monitoring sites do not have sufficient data to evaluate long-term trends in near-road $PM_{2.5}$ concentrations, analyses of the data at one near-road-like site in Elizabeth, NJ, [35] show that the annual average near-road increment has generally decreased between 1999 and 2017 from about 2.0 μg/m³ to about 1.3 μg/m³ (U.S. EPA, 2022b, section 2.3.2.1).

Ambient $PM_{2.5}$ concentrations can exhibit a diurnal cycle that varies due to impacts from intermittent emission sources, meteorology, and atmospheric chemistry. The $PM_{2.5}$ monitoring network in the U.S. has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations that reflect this diurnal variation. The 2019 ISA describes a two-peaked diurnal pattern in urban areas, with morning peaks attributed to rush-hour traffic and afternoon peaks attributed to a combination of rush hour traffic, decreasing atmospheric dilution, and nucleation (U.S. EPA, 2019a, section 2.5.2.3, Figure 2–32). Because a focus on annual average and 24-hour average $PM_{2.5}$ concentrations could mask subdaily patterns, and because some health studies examine PM exposure durations shorter than 24-hours, it is useful to understand the broader distribution of subdaily $PM_{2.5}$ concentrations across the U.S. The 2022 PA presents information on the frequency distribution of 2-hour average $PM_{2.5}$ mass concentrations from all FEM $PM_{2.5}$ monitors in the U.S. for 2017–2019. At sites meeting the current primary $PM_{2.5}$ standards, these 2-hour concentrations generally remain below 10 μg/m³, and rarely exceed 30 μg/m³. Two-hour concentrations are higher at sites violating the current standards, generally remaining below 16 μg/m³ and rarely exceeding 80 μg/m³ (U.S. EPA, 2022b, section 2.3.2.2.3). The extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations is shifted higher during the warmer months, generally corresponding to the period of peak wildfire frequency (April to September) in the U.S. At sites meeting the current primary standards, the highest 2-hour concentrations measured rarely occur outside of the period of peak wildfire frequency. Most of the sites measuring

[32] 40 CFR part 58, app. D, 4.7.1(b)(2).

[33] See *https://www.epa.gov/air-trends/particulate-matter-pm25-trends* for up-to-date $PM_{2.5}$ trends information.

[34] A design value is considered valid if it meets the data handling requirements given in appendix N to 40 CFR part 50.

[35] The Elizabeth Lab site in Elizabeth, NJ, is situated approximately 30 meters from travel lanes of the Interchange 13 toll plaza of the New Jersey Turnpike and within 200 meters of travel lanes for Interstate 278 and the New Jersey Turnpike.

these very high concentrations are in the northwestern U.S. and California, where wildfires have been relatively common in recent years (see U.S. EPA, 2022b, Appendix A, Figure A–1). When the period of peak wildfire frequency is excluded from the analysis, the extreme upper end of the distribution is reduced (U.S. EPA, 2022b, section 2.3.2.2.3).

b. $PM_{2.5}$ Components

Based on recent air quality data, the major chemical components of $PM_{2.5}$ have distinct spatial distributions. Sulfate concentrations tend to be highest in the eastern U.S., while in the Ohio Valley, Salt Lake Valley, and California nitrate concentrations are highest, and relatively high concentrations of organic carbon are widespread across most of the continental U.S. (U.S. EPA, 2022b, section 2.3.2.3). Elemental carbon, crustal material, and sea salt are found to have the highest concentrations in the northeast U.S., southwest U.S., and coastal areas, respectively.

An examination of $PM_{2.5}$ composition trends can provide insight into the factors contributing to overall reductions in ambient $PM_{2.5}$ concentrations. The biggest change in $PM_{2.5}$ composition that has occurred in recent years is the reduction in sulfate concentrations due to reductions in SO_2 emissions. Between 2000 and 2015, the nationwide annual average sulfate concentration decreased by 17% at urban sites and 20% at rural sites. This change in sulfate concentrations is most evident in the eastern U.S. and has resulted in organic matter or nitrate now being the greatest contributor to $PM_{2.5}$ mass in many locations (U.S. EPA, 2019a, Figure 2–19). The overall reduction in sulfate concentrations has contributed substantially to the decrease in national average $PM_{2.5}$ concentrations as well as the decline in the fraction of PM_{10} mass accounted for by $PM_{2.5}$ (U.S. EPA, 2019a, section 2.5.1.1.6; U.S. EPA, 2022b, section 2.3.1).

c. PM_{10}

At long-term monitoring sites in the U.S., the 2017–2019 average of 2nd highest 24-hour PM_{10} concentration was 68 $\mu g/m^3$ (with 10th and 90th percentiles at 28 and 124 $\mu g/m^3$, respectively) (U.S. EPA, 2022b, section 2.3.2.4).[36] The highest PM_{10} concentrations tend to occur in the western U.S. Seasonal analyses indicate that ambient PM_{10} concentrations are generally higher in the summer months than at other times of year, though the most extreme high concentration events are more likely in the spring (U.S. EPA, 2019a, Table 2–5). This is due to fact that the major PM_{10} emission sources, dust and agriculture, are more active during the warmer and drier periods of the year.

Recent ambient PM_{10} concentrations reflect reductions that have occurred across much of the U.S. (U.S. EPA, 2022b, section 2.3.2.4). From 2000 to 2019, 2nd highest 24-hour PM_{10} concentrations have declined by about 46% (U.S. EPA, 2022b, section 2.3.2.4).[37] Analyses at individual monitoring sites indicate that annual average PM_{10} concentrations have generally declined at most sites across the U.S., with much of the decrease in the eastern U.S. associated with reductions in $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.2.4). Annual 2nd highest 24-hour PM_{10} concentrations have generally declined in the eastern U.S., while concentrations in much of the midwest and western U.S. have remained unchanged or increased since 2000 (U.S. EPA, 2022b, section 2.3.2.4).

Compared to previous reviews, data available from the NCore monitoring network in the current reconsideration allows a more comprehensive analysis of the relative contributions of $PM_{2.5}$ and $PM_{10–2.5}$ to PM_{10} mass. $PM_{2.5}$ generally contributes more to annual average PM_{10} mass in the eastern U.S. than the western U.S. (U.S. EPA, 2022b, Figure 2–23). At most sites in the eastern U.S., the majority of PM_{10} mass is comprised of $PM_{2.5}$. As ambient $PM_{2.5}$ concentrations have declined in the eastern U.S. (U.S. EPA, 2022b, section 2.3.2.2), the ratios of $PM_{2.5}$ to PM_{10} have also declined. For sites with days having concurrently very high $PM_{2.5}$ and PM_{10} concentrations (U.S. EPA, 2022b, Figure 2–24), the $PM_{2.5}/PM_{10}$ ratios are typically higher than the annual average ratios. This is particularly true in the northwestern U.S. where the high PM_{10} concentrations can occur during wildfires with high $PM_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.4).

d. $PM_{10–2.5}$

Since the 2012 review, the availability of $PM_{10–2.5}$ ambient concentration data has greatly increased because of additions to the $PM_{10–2.5}$ monitoring capabilities to the national monitoring network. As illustrated in the 2022 PA (U.S. EPA, 2022b, section 2.3.2.5), annual average and 98th percentile $PM_{10–2.5}$ concentrations exhibit less distinct differences between the eastern and western U.S. than for either $PM_{2.5}$ or PM_{10}.

Due to the short atmospheric lifetime of $PM_{10–2.5}$ relative to $PM_{2.5}$, many of the high concentration sites are isolated and likely near emission sources associated with wind-blown and fugitive dust. The spatial distributions of annual average and 98th percentile concentrations of $PM_{10–2.5}$ are more similar than that of $PM_{2.5}$, suggesting that the same dust-related emission sources are affecting both long-term and episodic concentrations (U.S. EPA, 2022b, Figure 2–25). The highest concentrations of $PM_{10–2.5}$ are in the southwest U.S. where widespread dry and windy conditions contribute to wind-blown dust emissions. Additionally, compared to $PM_{2.5}$ and PM_{10}, changes in $PM_{10–2.5}$ concentrations have been small in magnitude and inconsistent in direction (U.S. EPA, 2022b, Figure 2–25). The majority of $PM_{10–2.5}$ sites in the U.S. do not have a concentration trend from 2000–2019, reflecting the relatively consistent level of dust emissions across the U.S. during the same time period (U.S. EPA, 2022b, section 2.3.2.5).[38]

e. UFP

Compared to $PM_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. In the published literature, annual average particle number concentrations reaching about 20,000 to 30,000 cm^3 have been reported in U.S. cities (U.S. EPA, 2019a). In addition, based on UFP measurements in two urban areas (New York City, Buffalo) and at a background site (Steuben County) in New York, there is a pronounced difference in particle number concentration between different types of locations (U.S. EPA, 2022b, Figure 2–26; U.S. EPA, 2019a, Figure 2–18). Urban particle number counts were several times higher than at the background site, and the highest particle number counts in an urban area with multiple sites (Buffalo) were observed at a near-road location (U.S. EPA, 2022b, section 2.3.2.6).

Long-term trends in UFP are not routinely available at U.S. monitoring

[36] The form of the current 24-hour PM_{10} standard is one-expected-exceedance, averaged over three years.

[37] For more information, see *https://www.epa.gov/air-trends/particulate-matter-pm10-trends#pmnat.*

[38] PM from dust emissions in the National Emissions Inventory (NEI) remain fairly consistent from year-to-year, except when there are severe weather incursions or there is a dust event that transports or causes major local dust storms to occur (particularly in the western U.S.). These dust events and weather incursions needed to effect dust emissions on a national level are not common and only seldomly occur. In the emissions trends analysis presented in the 2022 PA (U.S. EPA, 2022b, section 2.1.1), dust is included in the NEI sector labeled ''miscellaneous.''

sites. At one background site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2019, closely matching the reductions in annual $PM_{2.5}$ mass over that same period (U.S. EPA, 2022b, section 2.3.2.6). In addition, a small number of published studies have examined UFP trends over time. While limited, these studies also suggest that UFP number concentrations have declined over time along with decreases in $PM_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.6). However, the relationship between changes in ambient $PM_{2.5}$ and UFPs cannot be comprehensively characterized due to the high variability and limited monitoring of UFPs (U.S. EPA, 2022b, section 2.3.2.6).

5. Characterizing Ambient $PM_{2.5}$ Concentrations for Exposure

Epidemiologic studies use various methods to characterize exposure to ambient $PM_{2.5}$. The methods used to estimate $PM_{2.5}$ concentrations can vary from traditional methods using monitoring data from ground-based monitors to newer methods using more complex hybrid modeling approaches. Studies using hybrid modeling approaches aim to broaden the spatial coverage, as well as estimate more spatially-resolved ambient $PM_{2.5}$ concentrations, by expanding beyond just those areas with monitors and providing estimates in areas that do not have ground-based monitors (*i.e.,* areas that are generally less densely populated and tend to have lower $PM_{2.5}$ concentrations) and at finer spatial resolutions (*e.g.,* 1 km x 1 km grid cells). Ground-based $PM_{2.5}$ monitors are generally sited in areas of expected maximum concentration. As such, the hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in doing so, the studies that utilize these methods tend to report lower mean $PM_{2.5}$ concentrations than monitor-based approaches. Further, other aspects of the approaches applied in the various epidemiologic studies to estimate $PM_{2.5}$ exposure and/or to calculate the related study-reported mean concentration (*i.e.,* population weighting, trim mean approaches) can affect those data values. More detail related to hybrid modeling methods, performance of the methods, and how the reported mean concentrations compare across approaches is provided in section 2.3.3.2 of the 2022 PA (U.S. EPA, 2022b). The subsections below discuss the characterization of $PM_{2.5}$ concentrations based on monitoring data (I.D.5.a) and using hybrid modeling approaches (I.D.5.b).

a. Predicted Ambient $PM_{2.5}$ and Exposure Based on Monitored Data

Ambient concentrations of $PM_{2.5}$ are often characterized using measurements from national monitoring networks due to the accuracy and precision of the measurements and the public availability of data. For applications requiring $PM_{2.5}$ characterizations across large areas or provide complete coverage from the site measurements, data interpolation and averaging techniques (such as Average Nearest Neighbor tools, and area-wide or population-weighted averaging of monitors) are sometimes used (U.S. EPA, 2019a, chapter 3).

For an area to meet the NAAQS, all valid design values [39] in that area, including the highest annual and 24-hour design values, must be at or below the levels of the standards. Because the monitoring network siting requirements are specified to capture the high $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.2.3), areas meeting an annual $PM_{2.5}$ standard with a particular level would be expected to have long-term average monitored $PM_{2.5}$ concentrations (*i.e.,* averaged across space and over time in the area) somewhat below that standard level. This means that the $PM_{2.5}$ design value in an area is associated with a distribution of $PM_{2.5}$ concentrations in that area, and, based on monitoring siting requirements, should represent the highest concentration location applicable to be monitored under the $PM_{2.5}$ NAAQS. Analyses in the 2022 PA indicate that, based on recent air quality in U.S. CBSAs, maximum annual $PM_{2.5}$ design values are often 10% to 20% higher than annual average concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2022b, section 2.3.3.1, Figures 2–28 and 2–29). This difference between the maximum annual design value and the average concentration in an area can vary, depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. Given that higher $PM_{2.5}$ concentrations have been reported at some near-road monitoring sites relative to the surrounding area (U.S. EPA, 2022b, section 2.3.2.2.2), recent requirements for $PM_{2.5}$ monitoring at near-road locations in large urban areas (U.S. EPA, 2022b, section 2.2.3.3) may increase the ratios of maximum design values to average annual design values in some areas. Such ratios may also depend on how the averages are calculated (*i.e.,* averaged across monitors versus across modeled grid cells, as described below in section I.5.b). Compared to annual design values, the analysis in the 2022 PA indicates a more variable relationship between maximum 24-hour $PM_{2.5}$ design values and annual average concentrations (U.S. EPA, 2022b, section 2.3.3.1, Figure 2–29).

b. Comparison of $PM_{2.5}$ Hybrid Modeling Approaches in Estimating Exposure and Relative to Design Values

Two types of hybrid approaches that have been utilized in several key $PM_{2.5}$ epidemiologic studies in the 2019 ISA and ISA Supplement include neural network approaches and a satellite-based method with regression of residual $PM_{2.5}$ with land-use and other variables to improve estimates of $PM_{2.5}$ concentration in the U.S. As such, the 2022 PA further compares these two types of approaches across various scales (*e.g.,* CBSA versus nationwide), taking into account population weighting approaches utilized in epidemiologic studies when estimating $PM_{2.5}$ exposure (U.S. EPA, 2022b, section 2.3.3.2.4). Additionally, the 2022 PA assesses how average $PM_{2.5}$ concentrations computed in epidemiologic studies using these hybrid surfaces compare to the maximum design values measured at ground-based monitors. For this assessment, the 2022 PA evaluates the DI2019 [40] and HA2020 [41] hybrid surfaces, surfaces that are used in several of the key epidemiologic studies in the 2022 PA. This analysis is intended to help inform how the magnitude of the overall study-reported mean $PM_{2.5}$ concentrations in epidemiologic studies may be

[39] For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of 24-hour $PM_{2.5}$ concentrations, averaged over three years (appendix N of 40 CFR part 50).

[40] This analysis includes an updated version of the surface used in Di et al. (2016). Predictions in Di et al. (2016) were for 2000 to 2012 using a neural network model. The Di et al. (2019) study improved on that effort in several ways. First, a generalized additive model was used that accounted for geographic variations in performance to combine predictions from three models (neural network, random forest, and gradient boosting) to make the final optimal $PM_{2.5}$ predictions. Second, the datasets were updated that were used in model training and included additional variables such as 12-km CMAQ modeling as predictors. Finally, more recent years were included in the Di et al. (2019) study.

[41] The HA2020 field is based on the V4.NA.03 product available at: *https://sites.wustl.edu/acag/datasets/surface-pm2-5/*. The name ''HA2020'' comes from the references for this product (Hammer et al., 2020; van Donkelaar et al., 2019).

influenced by the approach used to compute that mean and how that value might compare to monitor reported concentrations. The $PM_{2.5}$ standards are expected to achieve a pattern of air quality through the attainment of a specific design value at each monitor in the monitoring network. As a result, it is important to be able to assess the relationship between monitor concentrations and patterns of air quality evaluated in the epidemiologic studies.

In estimating exposure, some studies focus on estimating concentrations in urban areas, while others examine the entire U.S. or large portions of the country. In general, the areas that are not included in the CBSA-only analysis tend to be more rural or less densely populated areas, tend to have lower $PM_{2.5}$ concentrations, and likely correspond to those locations where monitoring data availability is limited or nonexistent (U.S. EPA, 2022b, section 2.3.3.2.4, Figure 2–37). To evaluate the differences in mean $PM_{2.5}$ concentrations across different spatial scales, the 2022 PA analysis compares the DI2019 and HA2020 surfaces. At the national scale, the two surfaces generally produce similar average annual $PM_{2.5}$ concentrations, with the DI2019 surface being slightly higher compared to the HA2020 surface. The average annual $PM_{2.5}$ concentrations are also slightly higher using the DI2019 surface compared to the HA2020 surface when the analyses are conducted for CBSAs. Also, regardless of which surface is used, the average annual and 3-year average of the average annual $PM_{2.5}$ concentrations for the CBSA-only analyses are somewhat higher than for the nationwide analyses (4–8% higher) (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–5).[42] Overall, these analyses suggest that there are only slight differences in the average $PM_{2.5}$ concentrations depending on the hybrid modeling method employed, though including other hybrid modeling methods in this comparison could result in larger differences.

The 2022 PA next evaluates how the averages of the hybrid model surfaces compare to regulatory design values using both the DI2019 and HA2020 surfaces and how population weighting influences the mean $PM_{2.5}$ concentration.[43] As presented in the 2022 PA, the results using the DI2019 and HA2020 surfaces are similar for the average annual $PM_{2.5}$ concentrations, for each 3-year period. When population weighting is not applied, the average annual $PM_{2.5}$ concentrations generally range from 7.0 to 8.6 $\mu g/m^3$. When population weighting is applied, the average annual $PM_{2.5}$ concentrations are slightly higher, ranging from 8.2 to 10.2 $\mu g/m^3$. As with CBSAs versus the national comparison above, population weighting results in a higher average $PM_{2.5}$ concentration than when population weighting is not applied (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–7). For the CBSAs included in the population weighted analyses, the average maximum annual design values generally range from 9.5 to 11.7 $\mu g/m^3$. The results are similar for both the DI2019 and HA2020 surfaces and the maximum annual $PM_{2.5}$ design values measured at the monitors are often 40% to 50% higher than average annual $PM_{2.5}$ concentrations predicted by hybrid modeling methods when population weighting is not applied. However, when population weighting is applied, the ratio of the maximum annual $PM_{2.5}$ design values to the predicted average annual $PM_{2.5}$ concentrations are lower than when population weighting is not applied, with monitored design values generally 15% to 18% higher than population-weighted hybrid modeling average annual $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–7).

6. Background PM

In this reconsideration, background PM is defined as all particles that are formed by sources or processes that cannot be influenced by actions within the jurisdiction of concern. U.S. background PM is defined as any PM formed from emissions other than U.S. anthropogenic (*i.e.,* manmade) emissions. Potential sources of U.S. background PM include both natural sources (*i.e.,* PM that would exist in the absence of any anthropogenic emissions of PM or PM precursors) and transboundary sources originating outside U.S. borders. Background PM is discussed in more detail in the 2022 PA (U.S. EPA, 2022b, section 2.4). At annual and national scales, estimated background PM concentrations in the U.S. are small compared to contributions from domestic anthropogenic sources.[44] For example, based on zero-out modeling in the last review of the PM NAAQS, annual background $PM_{2.5}$ concentrations were estimated to range from 0.5–3 $\mu g/m^3$ across the sites examined. In addition, speciated monitoring data from IMPROVE sites can provide some insights into how contributions from different sources, including sources of background PM, may have changed over time. Such data suggests the estimates of background concentrations using speciated monitoring data from IMPROVE monitors are around 1–3 $\mu g/m^3$ and have not changed significantly since the 2012 review. Contributions to background PM in the U.S. result mainly from sources within North America. Contributions from intercontinental events have also been documented (*e.g.,* transport from dust storms occurring in deserts in North Africa and Asia), but these events are less frequent and represent a relatively small fraction of background PM in most of the U.S. (U.S. EPA, 2022b, section 2.4).

II. Rationale for Decisions on the Primary $PM_{2.5}$ Standards

This section presents the rationale for the Administrator's decision to revise the primary annual $PM_{2.5}$ standard down to a level of 9 $\mu g/m^3$ and retain the primary 24-hour $PM_{2.5}$ standard. This rationale is based on a thorough review of the scientific evidence generally published through January 2018,[45] as evaluated in the 2019 ISA (U.S. EPA, 2019a), on the human health effects of $PM_{2.5}$ associated with long- and short-term exposures[46] to $PM_{2.5}$ in

[42] For the national scale, 3-year averages of the average annual $PM_{2.5}$ concentrations generally range from about 5.3 $\mu g/m^3$ to 8.1 $\mu g/m^3$, compared to the CBSA scale, which ranges from 5.7 $\mu g/m^3$ to 8.7 $\mu g/m^3$. (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–6).

[43] For this analysis, the 2022 PA includes CBSAs with three or more valid design values for the 3-year period. The regulatory design values for the CBSAs were calculated for each 3-year period for the CBSAs with 3 or more design values in each of the 3-year periods. Using the maximum design value for each CBSA and by each 3-year period, the ratio of maximum design values to modeled average annual $PM_{2.5}$ concentrations were calculated, for each 3-year period. More details about the analytical methods used for this analysis are described in section A.6 of Appendix A in the 2022 PA (U.S. EPA, 2022b).

[44] Sources that contribute to natural background PM include dust from the wind erosion of natural surfaces, sea salt, wildland fires, primary biological aerosol particles such as bacteria and pollen, oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosols (SOA), and geogenic sources such as sulfate formed from volcanic production of SO_2 and oceanic production of dimethyl-sulfide (U.S. EPA, 2022b, section 2.4). While most of these sources release or contribute predominantly to fine aerosol, some sources including windblown dust, and sea salt also produce particles in the coarse size range (U.S. EPA, 2019a, section 2.3.3).

[45] In addition to the 2020 review's opening ''call for information'' (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES–2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

[46] Short-term exposures are defined as those exposures occurring over hours up to 1 month,

the ambient air. Additionally, this rationale is based on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA, as evaluated in the ISA Supplement, that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA, generally through March 2021 (U.S. EPA, 2022a).[47] The Administrator's rationale also takes into account: (1) The 2022 PA evaluation of the policy-relevant information in the 2019 ISA and ISA Supplement and presentation of quantitative analyses of air quality and health risks; (2) CASAC advice and recommendations; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator's decisions and its foundations, section II.A provides background on the general approach for this reconsideration and the basis for the existing standard, and also presents brief summaries of key aspects of the currently available health effects and risk information. Section II.B summarizes the CASAC advice and the basis for the proposed conclusions, addresses public comments received on the proposal and presents the Administrator's conclusions on the adequacy of the current standards, drawing on consideration of the scientific evidence and quantitative risk information, advice from the CASAC, and comments from the public. Section II.C summarizes the Administrator's decision on the primary $PM_{2.5}$ standards.

A. Introduction

The general approach for this reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards is fundamentally based on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding primary $PM_{2.5}$ standards that protect public health with an adequate margin of safety. The EPA's assessments are primarily documented in the 2019 ISA, ISA Supplement, and 2022 PA, all of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 85 FR 4655, January 27, 2020; 86 FR 52673, September 22, 2021; 86 FR 54186, September 30, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022; 87 FR 22207, April 14, 2022; 87 FR 31965, May 26, 2022). In bridging the gap between the scientific assessments of the 2019 ISA and ISA Supplement and the judgments required of the Administrator in determining whether the current standards provide the requisite public health protection, the 2022 PA evaluates policy implications of the evaluation of the current evidence in the 2019 ISA and ISA Supplement, and the risk information documented in the 2022 PA. In evaluating the public health protection afforded by the current standards, the four basic elements of the NAAQS (*i.e.,* indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current primary $PM_{2.5}$ standards is a public health policy judgment to be made by the Administrator. In reaching conclusions with regard to the standards, the decision will draw on the scientific information and analyses about health effects and population risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive (also referred to as ''at-risk'') groups.[48]

1. Background on the Current Standards

The current primary $PM_{2.5}$ standards were retained in 2020 based on the scientific evidence and quantitative risk information available at that time, as well as the then-Administrator's judgments regarding the available health effects evidence and the appropriate degree of public health protection afforded by the existing standards (85 FR 82718, December 18, 2020). With the 2020 decision, the then-Administrator retained the primary annual $PM_{2.5}$ standard with its level of 12.0 $\mu g/m^3$ and retained the primary 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$. The key considerations and the then-Administrator's conclusions regarding the primary $PM_{2.5}$ standards in the 2020 review are summarized below.

The health effects evidence base available in the 2020 review included extensive evidence from previous reviews as well as the evidence that had emerged since the prior review had been completed in 2012. This evidence base, spanning several decades, documents the relationship between short- and long-term $PM_{2.5}$ exposure and mortality or serious morbidity effects. The evidence available in the 2019 ISA reaffirmed, and in some cases strengthened, the conclusions from the 2009 ISA regarding the health effects of $PM_{2.5}$ exposures (U.S. EPA, 2019a). Much of the evidence came from epidemiologic studies conducted in North America, Europe, or Asia examining short-term and long-term exposures that demonstrated generally positive, and often statistically significant, $PM_{2.5}$ health effect associations with a range of outcomes including non- accidental, cardiovascular, or respiratory mortality; cardiovascular- or respiratory-related hospitalizations or emergency department visits; and other mortality/morbidity outcomes (*e.g.,* lung cancer mortality or incidence, asthma development). Experimental evidence, as well as evidence from panel studies, strengthened support for potential biological pathways through which $PM_{2.5}$ exposures could lead to health effects reported in many population-based epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects.

whereas long-term exposures are defined as those exposures occurring over 1 month to years (U.S. EPA, 2019a, section P.3.1).

[47] The ISA Supplement represents an evaluation of recent studies that are of greatest policy relevance to the reconsideration of the 2020 final decision on the PM NAAQS. Specifically, the ISA Supplement focuses on studies of health effects for which the evidence in the 2019 ISA supported a ''causal relationship'' (*i.e.,* short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects) because those were the health effects that were most useful in informing conclusions in the 2020 PA. The ISA Supplement does not include an evaluation of studies for other $PM_{2.5}$-related health effects (U.S. EPA, 2022a).

[48] As noted in section I.A above, the legislative history describes such protection for the sensitive group of individuals and not for a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong, 2d Sess. 10 [1970]); see also *Am. Lung Ass'n* v. *EPA,* 134 F.3d 388, 389 (D.C. Cir. 1998).

Based on this evidence, the 2019 ISA concluded there to be a causal relationship between long- and short-term $PM_{2.5}$ exposure and mortality and cardiovascular effects, as well as likely to be causal relationships between long- and short-term $PM_{2.5}$ exposure and respiratory effects, and between long-term $PM_{2.5}$ exposure and cancer and nervous system effects (U.S. EPA, 2019a, section 1.7).

Epidemiologic studies reported $PM_{2.5}$ health effect associations with mortality and/or morbidity across multiple U.S. cities and in diverse populations, including in studies examining populations and lifestages that may be at increased risk of experiencing a $PM_{2.5}$-related health effect (*e.g.,* older adults, children). The 2019 ISA cited extensive evidence indicating that ''both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects'' (U.S. EPA, 2019a, p. 12–1), including children and older adults, people with pre-existing respiratory or cardiovascular disease, minority populations, and low socioeconomic status (SES) populations.

The risk information available in the 2020 review included risk estimates for air quality conditions just meeting the existing primary $PM_{2.5}$ standards, and also for air quality conditions just meeting potential alternative standards. The general approach to estimating $PM_{2.5}$-associated health risks combined concentration-response (C–R) functions from epidemiologic studies with model-based $PM_{2.5}$ air quality surfaces, baseline health incidence data, and population demographics for 47 urban areas (U.S. EPA, 2020b, section 3.3, Figure 3–10, Appendix C). The risk assessment estimated that the existing primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. Uncertainty in risk estimates (*e.g.,* in the size of risk estimates) can result from a number of factors, including assumptions about the shape of the C–R relationship with mortality at low ambient $PM_{2.5}$ concentrations, the potential for confounding and/or exposure measurement error, and the methods used to adjust $PM_{2.5}$ air quality.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the primary $PM_{2.5}$ standards was with regard to the adequacy of the protection provided by the existing standards.

As an initial matter, the then-Administrator considered the range of scientific evidence evaluating these effects, including studies of at-risk populations, to inform his review of the primary $PM_{2.5}$ standards, placing the greatest weight on evidence of effects for which the 2019 ISA determined there to be a causal or likely to be causal relationship with long- and short-term $PM_{2.5}$ exposures (85 FR 82714–82715, December 18, 2020).

With regard to indicator, the then-Administrator recognized that, consistent with the evidence available in prior reviews, the scientific evidence continued to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures. He noted the 2020 PA conclusions that the information continued to support the $PM_{2.5}$ mass-based indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components, and too limited to support a distinct standard for the ultrafine fraction. Thus, the then-Administrator concluded that it was appropriate to retain $PM_{2.5}$ as the indicator for the primary standards for fine particles (85 FR 82715, December 18, 2020).

With respect to averaging time and form, the then-Administrator noted that the scientific evidence continued to provide strong support for health effects associations with both long-term (*e.g.,* annual or multi-year) and short-term (*e.g.,* mostly 24-hour) exposures to $PM_{2.5}$, consistent with the conclusions in the 2020 PA. In the 2019 ISA, epidemiologic and controlled human exposure studies examined a variety of $PM_{2.5}$ exposure durations. Epidemiologic studies continued to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour $PM_{2.5}$ averaging periods, and the EPA noted that associations with subdaily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019a, section 1.5.2.1; U.S. EPA, 2020b, section 3.5.2.2). In addition, controlled human exposure and panel-based studies of subdaily exposures typically examined subclinical effects, rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.,* mortality, hospitalizations). Taken together, the 2019 ISA concluded that epidemiologic studies did not indicate that subdaily averaging periods were more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, while controlled human exposure studies provided consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (*i.e.,* <30 minutes to 5 hours), exposure concentrations in the studies were well-above the ambient concentrations typically measured in locations meeting the existing standards (U.S. EPA, 2020b, section 3.2.3.1). Thus, these studies also did not suggest the need for additional protection against subdaily $PM_{2.5}$ exposures (U.S. EPA, 2020b, section 3.5.2.2). Therefore, the then-Administrator judged that the 24-hour averaging time remained appropriate (85 FR 82715, December 18, 2020).

With regard to the form of the 24-hour standard (98th percentile, averaged over three years), the then-Administrator noted that epidemiologic studies continued to provide strong support for health effect associations with short-term (*e.g.,* mostly 24-hour) $PM_{2.5}$ exposures (U.S. EPA, 2020b, section 3.5.2.3) and that controlled human exposure studies provided evidence for health effects following single short-term ''peak'' $PM_{2.5}$ exposures. Thus, the evidence supported retaining a standard focused on providing supplemental protection against short-term peak exposures and supported a 98th percentile form for a 24-hour standard. The then-Administrator further noted that this form also provided an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2020b, section 3.5.2.3). As such, the then-Administrator concluded that the available information supported retaining the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years) and annual standard (annual average, averaged over three years) (85 FR 82715, December 18, 2020).

With regard to the level of the standards, in reaching his final decision, the then-Administrator considered the large body of evidence presented and assessed in the 2019 ISA (U.S. EPA, 2019a), the policy-relevant and risk-based conclusions and rationales as presented in the 2020 PA (U.S. EPA, 2020b), advice from the CASAC, and public comments. In particular, in considering the 2019 ISA and 2020 PA, he considered key epidemiologic studies that evaluated associations between $PM_{2.5}$ air quality distributions and mortality and morbidity, including key accountability studies; the availability of experimental studies to support biological plausibility; controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures; air quality analyses; and the important uncertainties and limitations associated with the information (85 FR 82715, December 18, 2020).

As an initial matter, the then-Administrator considered the protection afforded by both the annual and 24-hour standards together against long- and short-term $PM_{2.5}$ exposures and health effects. The Administrator recognized that the annual standard was most effective in controlling ''typical'' $PM_{2.5}$ concentrations near the middle of the air quality distribution (*i.e.,* around the mean of the distribution), but also provided some control over short-term peak $PM_{2.5}$ concentrations. On the other hand, the 24-hour standard, with its 98th percentile form, was most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so also had an effect on annual average $PM_{2.5}$ concentrations. Thus, while either standard could be viewed as providing some measure of protection against both average exposures and peak exposures, the 24-hour and annual standards were not expected to be equally effective at limiting both types of exposures. Thus, consistent with previous reviews, the then-Administrator's consideration of the public health protection provided by the existing primary $PM_{2.5}$ standards was based on his consideration of the combination of the annual and 24-hour standards. Specifically, he recognized that the annual standard was more likely to appropriately limit the ''typical'' daily and annual exposures that are most strongly associated with the health effects observed in epidemiologic studies. The then-Administrator concluded that an annual standard (as the arithmetic mean, averaged over three years) remained appropriate for targeting protection against the annual and daily $PM_{2.5}$ exposures around the middle portion of the $PM_{2.5}$ air quality distribution. Further, recognizing that the 24-hour standard (with its 98th percentile form) was more directly tied to short-term peak $PM_{2.5}$ concentrations, and more likely to appropriately limit exposures to such concentrations, the then-Administrator concluded that the current 24-hour standard (with its 98th percentile form, averaged over three years) remained appropriate to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs. However, the then-Administrator recognized that changes in $PM_{2.5}$ air quality to meet an annual standard would likely result not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. The then-Administrator further recognized that changes in air quality to meet a 24-hour standard, with a 98th percentile form, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations (85 FR 82715–82716, December 18, 2020).

Thus, in considering the adequacy of the 24-hour standard, the then-Administrator noted the importance of considering whether additional protection was needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, he noted the limited utility of the animal toxicological studies in directly informing conclusions on the appropriate level of the standard given the uncertainty in extrapolating from effects in animals to those in human populations. The then-Administrator noted that controlled human exposure studies provided evidence for health effects following single, short-term $PM_{2.5}$ exposures that corresponded best to exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). However, most of these studies examined exposure concentrations considerably higher than are typically measured in areas meeting the standards (U.S. EPA, 2020b, section 3.2.3.1). In particular, controlled human exposure studies often reported statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the 2020 PA (U.S. EPA, 2020b, p. 3–49) noted that 2-hour ambient concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceeded 32 $\mu g/m^3$. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the primary $PM_{2.5}$ standards remained well-below the $PM_{2.5}$ exposure concentrations consistently shown in controlled human exposure studies to elicit effects (*i.e.,* 99.9th percentile of 2-hour concentrations at these sites is 68 $\mu g/m^3$ during the warm season). Thus, the experimental evidence did not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the 24-hour and the annual standards (U.S. EPA, 2020b, section 3.2.3.1; 85 FR 82716, December 18, 2020).

With respect to the epidemiologic evidence, the then-Administrator noted that the studies did not indicate that associations in those studies were strongly influenced by exposures to peak concentrations in the air quality distribution and thus did not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations (U.S. EPA, 2020b, section 3.5.1). The then-Administrator noted that this was consistent with CASAC consensus support for retaining the current 24-hour standard. Thus, the then-Administrator concluded that the 24-hour standard with its level of 35 $\mu g/m^3$ was adequate to provide supplemental protection (*i.e.,* beyond that provided by the annual standard alone) against short-term exposures to peak $PM_{2.5}$ concentrations (85 FR 82716, December 18, 2020).

With regard to the level of the annual standard, the then-Administrator recognized that the annual standard, with its form based on the arithmetic mean concentration, was most appropriately meant to limit the ''typical'' daily and annual exposures that were most strongly associated with the health effects observed in epidemiologic studies. However, the then-Administrator also noted that while epidemiologic studies examined associations between distributions of $PM_{2.5}$ air quality and health outcomes, they did not identify particular $PM_{2.5}$ exposures that cause effects and thus, they could not alone identify a specific level at which the standard should be set, as such a determination necessarily required the then-Administrator's judgment. Thus, consistent with the approaches in previous NAAQS reviews, the then-Administrator recognized that any approach that used epidemiologic information in reaching decisions on what standards are appropriate necessarily required judgments about how to translate the information from the epidemiologic studies into a basis for appropriate standards. This approach included consideration of the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiologic studies. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the Clean Air Act (CAA) (85 FR 82716, December 18, 2020).

The then-Administrator emphasized uncertainties and limitations that were present in epidemiologic studies in previous reviews and persisted in the 2020 review. These uncertainties

included exposure measurement error, potential confounding by copollutants, increasing uncertainty of associations at lower $PM_{2.5}$ concentrations, and heterogeneity of effects across different cities or regions (85 FR 82716, December 18, 2020). The then-Administrator also noted the advice given by the CASAC on this matter. As described in section I.C.5 above, the CASAC did not reach consensus on the adequacy of the primary annual $PM_{2.5}$ standard. ''Some CASAC members'' expressed support for retaining the primary annual $PM_{2.5}$ standard while ''other members'' expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p. 1 of consensus letter). The CASAC members who supported retaining the annual standard expressed their concerns with the epidemiologic studies, asserting that these studies did not provide a sufficient basis for revising the existing standards. They also identified several key concerns regarding the associations reported in epidemiologic studies and concluded that ''while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations'' (Cox, 2019b, p. 8 consensus responses).

Taking into consideration the views expressed by the CASAC members who supported retaining the annual standard, the then-Administrator recognized that epidemiologic studies examined associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they did not identify particular $PM_{2.5}$ exposures that cause effects (U.S. EPA, 2020b, section 3.1.2). While the Administrator remained concerned about placing too much weight on epidemiologic studies to inform conclusions on the adequacy of the primary standards, he noted the approach to considering such studies in the 2012 review. In the 2012 review, it was noted that the evidence of an association in any epidemiologic study was ''strongest at and around the long-term average where the data in the study are most concentrated'' (78 FR 3140, January 15, 2013). In considering the characterization of epidemiologic studies, the then-Administrator viewed that when assessing the mean concentrations of the key short-term and long-term epidemiologic studies in the U.S. that used ground-based monitoring (*i.e.,* those studies where the mean is most directly comparable to the current annual standard), the majority of studies had mean concentrations at or above the level of the existing annual standard, with the mean of the study-reported means or medians equal to 13.5 $\mu g/m^3$, a concentration level above the existing level of the primary annual standard of 12 $\mu g/m^3$. The then-Administrator further noted his caution in directly comparing the reported study mean values to the standard level given that study-reported mean concentrations, by design, are generally lower than the design value of the highest monitor in an area, which determines compliance. In the 2020 PA, analyses of recent air quality in U.S. CBSAs indicated that maximum annual $PM_{2.5}$ design values for a given three-year period were often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020b, Appendix B, section B.7). He further noted his concern in placing too much weight on any one epidemiologic study but instead judged that it was more appropriate to focus on the body of studies together and therefore noted the calculation of the mean of study-reported means (or medians). Thus, while the then-Administrator was cautious in placing too much weight on the epidemiologic evidence alone, he noted that: (1) The reported mean concentration in the majority of the key U.S. epidemiologic studies using ground-based monitoring data were above the level of the existing annual standard; (2) the mean of the reported study means (or medians) (*i.e.,* 13.5 $\mu g/m^3$) was above the level of the current standard; [49] (3) air quality analyses showed the study means to be lower than their corresponding design values by 10–20%; and (4) these analyses must be considered in light of uncertainties inherent in the epidemiologic evidence. When taken together, the then-Administrator judged that, even if it were appropriate to place more weight on the epidemiologic evidence, this information did not call into question the adequacy of the current standards (85 FR 82716–17, December 18, 2020).

In addition to the evidence, the then-Administrator also considered the potential implications of the risk assessment. He noted that all risk assessments have limitations and that he remained concerned about the uncertainties in the underlying epidemiologic data used in the risk assessment. The then-Administrator also noted that in previous reviews, these uncertainties and limitations have often resulted in less weight being placed on quantitative estimates of risk than on the underlying scientific evidence itself (*e.g.,* 78 FR 3086, 3098–99, January 15, 2013). These uncertainties and limitations included uncertainty in the shapes of C–R functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiologic study (U.S. EPA, 2020b, section 3.3.2.4). Additionally, the then-Administrator noted similar concern expressed by some members of the CASAC who support retaining the existing standards; they highlighted similar uncertainties and limitations in the risk assessment (Cox, 2019b). In light of all of this, the then-Administrator judged it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching conclusions about the level of the primary $PM_{2.5}$ standards (85 FR 82717, December 18, 2020).

The then-Administrator additionally considered an emerging body of evidence from accountability studies that examined past reductions in ambient $PM_{2.5}$ and the degree to which those reductions resulted in public health improvements. While the then-Administrator agreed with public commenters that well-designed and conducted accountability studies can be informative, he viewed the interpretation of such studies in the context of the primary $PM_{2.5}$ standards as complicated by the fact that some of the available studies had not evaluated $PM_{2.5}$ specifically (*e.g.,* as opposed to PM_{10} or total suspended particulates), did not show changes in $PM_{2.5}$ air quality, or had not been able to disentangle health impacts of the interventions from background trends in health (U.S. EPA, 2020b, section 3.5.1). He further recognized that the small number of available studies that did report public health improvements following past declines in ambient $PM_{2.5}$ had not examined air quality meeting the existing standards (U.S. EPA, 2020b, Table 3–3). This included U.S. studies that reported increased life expectancy, decreased mortality, and decreased respiratory effects following past declines in ambient $PM_{2.5}$ concentrations. Such studies examined ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* prior to the reductions being evaluated) ranging from about 13.2 to >20$\mu g/m^3$ (*i.e.,* U.S. EPA, 2020b, Table 3–3). Given the lack of available accountability studies

[49] The median of the study-reported mean (or median) $PM_{2.5}$ concentrations is 13.3 $\mu g/m^3$, which was also above the level of the existing standard.

reporting public health improvements attributable to reductions in ambient $PM_{2.5}$ in locations meeting the existing standards, together with his broader concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the existing standards, the then-Administrator judged that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the existing primary $PM_{2.5}$ standards (85 FR 82717, December 18, 2020).

When the above considerations were taken together, the then-Administrator concluded that the scientific evidence assessed in the 2019 ISA, together with the analyses in the 2020 PA based on that evidence and consideration of CASAC advice and public comments, did not call into question the adequacy of the public health protection provided by the existing annual and 24-hour $PM_{2.5}$ standards. In particular, the then-Administrator judged that there was considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below the concentrations achieved under the existing primary standards and that, therefore, standards more stringent than the existing standards (*e.g.,* with lower levels) were not supported. That is, he judged that more stringent standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflected the Administrator's consideration of the uncertainties in the potential implications of the lower end of the air quality distributions from the epidemiologic studies due in part to the lack of supporting evidence from experimental studies and retrospective accountability studies conducted at $PM_{2.5}$ concentrations meeting the existing standards (85 FR 82717, December 18, 2020).

In reaching this conclusion in the 2020 review, the then-Administrator judged that the existing standards provided an adequate margin of safety. With respect to the annual standard, the level of 12 $\mu g/m^3$ was below the lowest ''starting'' concentration (*i.e.,* 13.2 $\mu g/m^3$) in the available accountability studies that showed public health improvements attributable to reductions in ambient $PM_{2.5}$. In addition, while the then-Administrator placed less weight on the epidemiologic evidence for selecting a standard, he noted that the level of the annual standard was below the reported mean (and median) concentrations in the majority of the key U.S. epidemiologic studies using ground-based monitoring data (noting that these means tend to be 10–20% lower than their corresponding area design values which is the more relevant metric when considering the level of the standard) and below the mean of the reported means (or medians) of these studies (*i.e.,* 13.5 $\mu g/m^3$). In addition, the then-Administrator recognized that concentrations in areas meeting the existing 24-hour and annual standards remained well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in human exposure studies (85 FR 82717–82718, December 18, 2020).

In addition, based on the then-Administrator's review of the science in the 2020 review, including controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures, the epidemiologic studies, and accountability studies conducted at levels just above the existing annual standard, he judged that the degree of public health protection provided by the existing annual standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, led the then- Administrator to conclude that standards less stringent than the existing standards (*e.g.,* with higher levels) were also not supported (85 FR 82718, December 18, 2020).

In reaching his final decision in the 2020 review, the then-Administrator concluded that the scientific evidence and technical information continued to support the existing annual and 24-hour $PM_{2.5}$ standards. This conclusion reflected the then-Administrator's view that there were important limitations and uncertainties that remained in the evidence. The then-Administrator concluded that these limitations contributed to considerable uncertainty regarding the potential public health implications of revising the existing primary $PM_{2.5}$ standards. Given this uncertainty, and noting the advice from some CASAC members, he concluded that the primary $PM_{2.5}$ standards, including the indicators ($PM_{2.5}$), averaging times (annual and 24-hour), forms (arithmetic mean and 98th percentile, averaged over three years) and levels (12.0 $\mu g/m^3$, 35 $\mu g/m^3$), when taken together, remained requisite to protect the public health. Therefore, in the 2020 review, the Administrator reached the conclusion that the primary 24-hour and annual $PM_{2.5}$ standards, together, were requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and retained the standards, without revision (85 FR 82718, December 18, 2020).

2. Overview of the Health Effects Evidence

The information summarized here and further detailed in section II.B of the proposal (88 FR 5580, January 27, 2023), is an overview of the policy-relevant aspects of the health effects evidence available in this reconsideration; the assessment of this evidence is documented in the 2019 ISA (U.S. EPA, 2019a) and ISA Supplement (U.S. EPA, 2022a) and its policy implications are further discussed in the 2022 PA (U.S. EPA, 2022b). While the 2019 ISA provides the broad scientific foundation for this reconsideration, additional literature has become available since the cutoff date of the 2019 ISA that expands the body of evidence related to mortality and cardiovascular effects for both short- and long-term $PM_{2.5}$ exposure, which can inform the Administrator's judgment on the adequacy of the current primary $PM_{2.5}$ standards. As such, the ISA Supplement builds on the information presented within the 2019 ISA with a targeted identification and evaluation of new scientific information (U.S. EPA, 2022a, section 1.2). The ISA Supplement focuses on $PM_{2.5}$ health effects evidence where the 2019 ISA concludes a ''causal relationship,'' because such health effects are given the most weight in an Administrator's decisions in a NAAQS review. As such, in selecting the health effects to evaluate within the ISA Supplement (*i.e.,* newly available evidence related to short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects), the primary rationale is based on the causality determinations for health effect categories presented in the 2019 PM ISA, and the subsequent use of the health effects evidence in the 2020 PM PA. Specifically, U.S. and Canadian epidemiologic studies for mortality and cardiovascular effects, along with controlled human exposure studies associated with cardiovascular effects at near ambient concentrations, were considered to be of greatest utility in informing the Administrator's conclusions on the adequacy of the current primary $PM_{2.5}$ standards. Additionally, studies examining associations outside the U.S. or Canada reflect air quality and exposure patterns that may be less typical of the U.S., and thus less likely to be informative for purposes of reviewing the NAAQS (U.S. EPA, 2022b, p.1–3). While the ISA Supplement does not include information for health effects other than mortality and cardiovascular effects, the

scientific evidence for other health effect categories is evaluated in the 2019 ISA, which in combination with the ISA Supplement represents the complete scientific record for the reconsideration of the 2020 final decision.

The ISA Supplement also assessed accountability studies because these types of epidemiologic studies were part of the body of evidence that was a focus of the 2020 review. Accountability studies inform our understanding of the potential for public health improvements as ambient $PM_{2.5}$ concentrations have declined over time. Further, the ISA Supplement considered studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.,* used alternative methods for confounder control),[50] given that such studies were highlighted by the CASAC and identified in public comments in the 2020 review. Since the literature cutoff date for the 2019 ISA, multiple accountability studies and studies that employ alternative methods for confounder control have become available for consideration in the ISA Supplement and, subsequently, in this reconsideration.

The ISA Supplement also considered recent health effects evidence that addresses key scientific issues where the literature has expanded since the completion of the 2019 ISA.[51] The 2019 ISA evaluated a couple of controlled human exposure studies that investigated the effect of exposure to near-ambient concentrations of $PM_{2.5}$ (U.S. EPA, 2019a, section 6.1.10 and 6.1.13). The ISA Supplement adds to this limited evidence, including a recent study conducted in young healthy individuals exposed to near-ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022a, section 3.3.1). Given the importance of identifying populations at increased risk of $PM_{2.5}$-related effects, the ISA Supplement also included epidemiologic or exposure studies that examined whether there is evidence of exposure or risk disparities by race/ethnicity or SES. These types of studies provide additional information related to factors that may increase risk of $PM_{2.5}$-related health effects and provide additional evidence for consideration by the Administrator in reaching conclusions regarding the adequacy of the current standards. In addition, the ISA Supplement evaluated studies that examined the relationship between short- and long-term $PM_{2.5}$ exposures and SARS-CoV–2 infection and/or COVID–19 death, as these studies are a new area of research and were raised by a number of public commenters in the 2020 review.

The evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards. The subsections below briefly summarize the nature of $PM_{2.5}$-related health effects (II.A.2.a), with a focus on those health effects for which the 2019 ISA concluded a ''causal'' or ''likely to be causal'' relationship, the potential public health implications and populations at risk (II.A.2.b), and $PM_{2.5}$ concentrations in key studies reporting health effects (II.A.2.c).

a. Nature of Effects

The evidence base available in the reconsideration includes decades of research on $PM_{2.5}$-related health effects (U.S. EPA, 2004b; U.S. EPA, 2009a; U.S. EPA, 2019a), including the full body of evidence evaluated in the 2019 ISA (U.S. EPA, 2019a), along with the targeted evaluation of recent evidence in the ISA Supplement (U.S. EPA, 2022a). In considering the available scientific evidence, the sections below, and in more detail in section II.B.1 of the proposal (88 FR 5580, January 27, 2023), summarize the relationships between long-and short-term $PM_{2.5}$ exposures and mortality (II.A.2.a.i), cardiovascular effects (II.A.2.a.ii), respiratory effects (II.A.2.a.iii), cancer (II.A.2.a.iv), nervous system effects (II.A.2.a.v) and other effects (II.A.2.a.vi). For these outcomes, the 2019 ISA concluded that the evidence supports either a ''causal'' or a ''likely to be causal'' relationship.[52]

i. Mortality

Long-Term $PM_{2.5}$ Exposures

In the 2012 review, the 2009 ISA reported that the evidence was ''sufficient to conclude that the relationship between long-term $PM_{2.5}$ exposures and mortality is causal'' (U.S. EPA, 2009a, p. 7–96). The strongest evidence supporting this conclusion was provided by epidemiologic studies, particularly those examining two seminal cohorts, the American Cancer Society (ACS) cohort and the Harvard Six Cities cohort. Analyses of the Harvard Six Cities cohort included evidence indicating that reductions in ambient $PM_{2.5}$ concentrations are associated with reduced mortality risk (Laden et al., 2006) and increases in life expectancy (Pope et al., 2009). Further support was provided by other cohort studies conducted in North America and Europe that reported positive associations between long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019a).

Cohort studies, which have become available since the completion of the 2009 ISA and evaluated in the 2019 ISA, continue to provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposures and mortality. These studies add support for associations with all-cause and total (non-accidental) mortality,[53] as well as with specific causes of mortality, including cardiovascular disease and respiratory disease (U.S. EPA, 2019a, section 11.2.2). Several of these studies conducted analyses over longer study durations and periods of follow-up than examined in the original ACS and Harvard Six Cities cohort studies and continue to report positive associations between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2019a, section 11.2.2.1; Figures 11–18 and 11–19). In addition to studies focusing on the ACS and Harvard Six Cities cohorts, additional studies examining other cohorts also provide evidence of consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality across a wide range of demographic groups (*e.g.,* age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques (U.S. EPA, 2019a, sections 11.2.2.1, 11.2.5; U.S. EPA, 2022a, Table 11–8). This includes some of the largest cohort studies conducted to date, such as analyses of the U.S. Medicare cohort that includes

[50] As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1–3): ''In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling methods. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.,* the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence.''

[51] As with the epidemiologic studies for long- and short-term $PM_{2.5}$ exposure and mortality and cardiovascular effects, epidemiologic studies of exposure or risk disparities and SARS–CoV–2 infection and/or COVID–19 death were limited to those conducted in the U.S. and Canada.

[52] In this reconsideration of the PM NAAQS, the EPA considers the full body of health evidence, placing the greatest emphasis on the health effects for which the evidence has been judged in the 2019 ISA to demonstrate a ''causal'' or ''likely to be causal'' relationship with $PM_{2.5}$ exposures.

[53] The majority of these studies examined non-accidental mortality outcomes, though some Medicare studies lack cause-specific death information and, therefore, examine total mortality.

nearly 61 million enrollees and studies that control for a range of individual and ecological covariates, including race, age, SES, smoking status, body mass index, and annual weather variables (*e.g.,* temperature, humidity) (U.S. EPA, 2019a).

In addition to those cohort studies evaluated in the 2019 ISA, recent North American cohort studies evaluated in the ISA Supplement continue to examine the relationship between long-term $PM_{2.5}$ exposure and mortality and report consistent, positive, and statistically significant associations. These recent studies also utilize large and demographically diverse cohorts that are generally representative of the national populations in both the U.S. and Canada. These ''studies published since the 2019 ISA support and extend the evidence base that contributed to the conclusion of a *causal relationship* between long-term $PM_{2.5}$ exposure and mortality'' (U.S. EPA, 2022a, section 3.2.2.2.1, Figure 3–19, Figure 3–20).

Furthermore, studies evaluated in the 2019 ISA and the ISA Supplement that examined cause-specific mortality expand upon previous research that found consistent, positive associations between $PM_{2.5}$ exposure and specific mortality outcomes, which include cardiovascular and respiratory mortality, as well as other mortality outcomes. For cardiovascular-related mortality, the evidence evaluated in the ISA Supplement is consistent with the evidence evaluated in the 2019 ISA with recent studies reporting positive associations with long-term $PM_{2.5}$ exposure. When evaluating cause-specific cardiovascular mortality, recent studies reported positive associations for a number of outcomes, such as ischemic heart disease (IHD) and stroke mortality (U.S. EPA, 2022a, Figure 3–23). Moreover, recent studies also provide some initial evidence that individuals with pre-existing health conditions, such as heart failure and diabetes, are at an increased risk of $PM_{2.5}$-related health effects (U.S. EPA, 2022a, section 3.2.2.4) and that these individuals have a higher risk of mortality overall, which was previously only examined in studies that used stratified analyses rather than a cohort of people with an underlying health condition (U.S. EPA, 2022a, section 3.2.2.4). With regard to respiratory mortality, epidemiologic studies evaluated in the 2019 ISA and ISA Supplement continue to provide support for associations between long-term $PM_{2.5}$ exposure and respiratory mortality (U.S. EPA, 2019a, section 5.2.10; U.S. EPA, 2022a, Table 3–2).

A series of epidemiologic studies evaluated in the 2019 ISA tested the hypothesis that past reductions in ambient $PM_{2.5}$ concentrations are associated with increased life expectancy or a decreased mortality rate and report that reductions in ambient $PM_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2022a, section 11.2.2.5). Pope et al. (2009) conducted a cross-sectional analysis using air quality data from 51 metropolitan areas across the U.S., beginning in the 1970s through the early 2000s, and found that a 10 μg/m³ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.61-year increase in life expectancy. In a subsequent analysis, the authors extended the period of analysis to include 2000 to 2007, a time period with lower ambient $PM_{2.5}$ concentrations and found a decrease in long-term $PM_{2.5}$ concentration continued to be associated with an increase in life expectancy, though the magnitude of the increase was smaller than during the earlier time period (*i.e.,* a 10 μg/m³ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.35-year increase in life expectancy) (Correia et al., 2013). Additional studies conducted in the U.S. or Europe similarly report that reductions in ambient $PM_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2022a, section 11.2.2.5).

Since the literature cutoff date for the 2019 ISA, a few epidemiologic studies were published that examined the relationship between long-term $PM_{2.5}$ exposure and life-expectancy (U.S. EPA, 2022a, section 3.2.1.3) and report results that are consistent with and expand upon the body of evidence from the 2019 ISA. For example, Bennett et al. (2019) reported that $PM_{2.5}$ concentrations above the lowest observed concentration (2.8 μg/m³) were associated with a 0.15 year decrease in national life expectancy for women and 0.13 year decrease in national life expectancy for men (U.S. EPA, 2022a, section 3.2.2.2.4, Figure 3–25). Another study compared participants living in areas with $PM_{2.5}$ concentrations >12 μg/m³ to participants living in areas with $PM_{2.5}$ concentrations <12 μg/m³ and reported that the number of years of life lost due to living in areas with higher $PM_{2.5}$ concentrations was 0.84 years over a 5-year period (Ward-Caviness et al., 2020; U.S. EPA, 2022a, section 3.2.2.2.4).

Additionally, a number of accountability studies, which are epidemiologic studies that evaluate whether an environmental policy or air quality intervention resulted in reductions in ambient air pollution concentrations and subsequent reductions in mortality or morbidity, have emerged and were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). For example, Sanders et al. (2020a) examined whether policy actions (*i.e.,* the first annual $PM_{2.5}$ NAAQS implementation rule in 2005 for the 1997 annual $PM_{2.5}$ standard with a 3-year annual average of 15.0 μg/m³) reduced $PM_{2.5}$ concentrations and mortality rates in Medicare beneficiaries between 2000–2013, and found that following implementation of the annual $PM_{2.5}$ NAAQS, annual $PM_{2.5}$ concentrations decreased by 1.59 μg/m³ (95% CI: 1.39, 1.80) which corresponded to a 0.93% reduction in mortality rates among individuals 65 years and older ([95% CI: 0.10%, 1.77%) in non-attainment counties relative to attainment counties.

The 2019 ISA also evaluated a small number of studies that used alternative methods for confounder control to further assess relationship between long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019a, section 11.2.2.4). In addition, multiple epidemiologic studies that implemented alternative methods for confounder control and were published since the literature cutoff date of the 2019 ISA were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). These studies used a variety of statistical methods including generalized propensity score (GPS), inverse probability weighting (IPW), and difference-in-difference (DID) to reduce uncertainties related to confounding bias in the association between long-term $PM_{2.5}$ exposure and mortality. These studies reported consistent positive associations between long-term $PM_{2.5}$ exposure and total mortality (U.S. EPA, 2022a, section 3.2.2.3), and provided further support for the associations reported in the cohort studies referenced above.

The 2019 ISA and ISA Supplement also evaluated the degree to which recent studies examining the relationship between long-term $PM_{2.5}$ exposure and mortality addressed key policy-relevant issues and/or previously identified data gaps in the scientific evidence, including methods to estimate exposure, methods to control for confounding (*e.g.,* co-pollutant confounding), the shape of the C–R relationship, as well as examining whether a threshold exists below which mortality effects do not occur. With respect to exposure assessment, based on its evaluation of the evidence, the 2019 ISA concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust

across recent analyses using various approaches to estimate $PM_{2.5}$ exposures (*e.g.,* based on monitors, models, satellite-based methods, or hybrid methods that combine information from multiple sources) (U.S. EPA, 2019a, section 11.2.5.1). Hart et al. (2015) report that correction for bias due to exposure measurement error increases the magnitude of the hazard ratios (confidence intervals widen but the association remains statistically significant), suggesting that failure to correct for exposure measurement error could result in attenuation or underestimation of risk estimates.

The 2019 ISA additionally concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust across statistical models that use different approaches to control for confounders or different sets of confounders (U.S. EPA, 2019a, sections 11.2.3 and 11.2.5), across diverse geographic regions and populations, and across a range of temporal periods including periods of declining PM concentrations (U.S. EPA, 2019a, sections 11.2.2.5 and 11.2.5.3). Additional evidence further demonstrates that associations with mortality remain robust in copollutants analyses (U.S. EPA, 2019a, section 11.2.3), and that associations persist in analyses restricted to long-term exposures (annual average $PM_{2.5}$ concentrations) below 12 μg/m^3 (Di et al., 2017b) or 10 μg/m^3 (Shi et al., 2016), indicating that risks are not disproportionately driven by the upper portions of the air quality distribution. Recent studies evaluated in the ISA Supplement further assess potential copollutant confounding and indicate that while there is some evidence of potential confounding of the $PM_{2.5}$-mortality association by copollutants in some of the studies (*i.e.,* those studies of the Mortality Air Pollution Associations in Low Exposure Environments (MAPLE) cohort), this result is inconsistent with other recent studies evaluated in the 2019 ISA that were conducted in the U.S. and Canada that found associations in both single and copollutant models (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4)

Additionally, a few studies use statistical techniques to reduce uncertainties related to potential confounding to further inform conclusions on causality for long-term $PM_{2.5}$ exposure and mortality, as further detailed in section II.B.1.a.i of the proposal (88 FR 5582, January 27, 2023), studies by Greven et al. (2011), Pun et al. (2017), and Eum et al. (2018) completed sensitivity analyses as part of their Medicare cohort study in which they decompose ambient $PM_{2.5}$ into ''spatial'' and ''spatiotemporal'' components in order to evaluate the potential for bias due to unmeasured spatial confounding. Pun et al. (2017) observed positive associations for the ''temporal'' variation model and approximately null associations for the ''spatiotemporal'' variation model for all causes of death except for COPD mortality. The difference in the results of these two models for most causes of death suggests the presence of unmeasured confounding, though the authors do not indicate anything about the direction or magnitude of this bias. It is important to note that the ''temporal'' and ''spatiotemporal'' coefficients are not directly comparable to the results of other epidemiologic studies when examined individually and can only be used in comparison with one another to evaluate the potential for unmeasured confounding bias. Eum et al. (2018) and Wu et al. (2020) also attempted to address long-term trends and meteorological variables as potential confounders and found that not adjusting for temporal trends could overestimate the association, while effect estimates in analyses that excluded meteorological variables remained unchanged compared to the main analyses. While results of these analyses suggest the presence of some unmeasured confounding, they do not indicate the direction or magnitude of the bias.[54]

An additional important consideration in characterizing the public health impacts associated with $PM_{2.5}$ exposure is whether C–R relationships are linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Studies evaluated in the 2019 ISA and the ISA Supplement examine this issue, and continue to provide evidence of linear, no-threshold relationships between long-term $PM_{2.5}$ exposures and all-cause and cause-specific mortality (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 3.2.2.2.7, Table 3–6). Across the studies evaluated in the 2019 ISA and the ISA Supplement, a variety of statistical methods have been used to assess whether there is evidence of deviations in linearity (U.S. EPA, 2019a, Table 11–7; U.S. EPA, 2022a, section 2.2.3.2). Studies have also conducted cut-point analyses that focus on examining risk at specific ambient $PM_{2.5}$ concentrations. Generally, the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations >8 μg/m^3. However, uncertainties remain about the shape of the C–R curve at $PM_{2.5}$ concentrations <8 μg/m^3, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2). There was also some limited evidence indicating that the slope of the C–R function may be steeper (supralinear) at lower concentrations for cardiovascular mortality (U.S. EPA, 2022a, section 3.1.1.2.6).

The biological plausibility of $PM_{2.5}$-attributable mortality is supported by the coherence of effects across scientific disciplines (*i.e.,* animal toxicological, controlled human exposure studies, and epidemiologic) when evaluating respiratory and cardiovascular morbidity effects, which are some of the largest contributors to total (nonaccidental) mortality. The 2019 ISA outlines the available evidence for biologically plausible pathways by which inhalation exposure to $PM_{2.5}$ could progress from initial events (*e.g.,* pulmonary inflammation, autonomic nervous system activation) to endpoints relevant to population outcomes, particularly those related to cardiovascular diseases such as ischemic heart disease, stroke and atherosclerosis (U.S. EPA, 2019a, section 6.2.1), and to metabolic effects, including diabetes (U.S. EPA, 2019a, section 7.3.1). The 2019 ISA notes ''more limited evidence from respiratory morbidity'' (U.S. EPA, 2019a, p. 11–101) such as development of chronic obstructive pulmonary disease (COPD) (U.S. EPA, 2019a, section 5.2.1) to support the biological plausibility of mortality due to long-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 11.2.1).

Taken together, epidemiologic studies, including those evaluated in the 2019 ISA and more recent studies evaluated in the ISA Supplement, consistently report positive associations between long-term $PM_{2.5}$ exposure and mortality across different geographic locations, populations, and analytic approaches (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4). As such, these studies reduce key uncertainties identified in previous reviews, including those related to potential

[54] In public comments on the 2019 draft PA, the authors of the Pun et al. (2017) study further note that ''the presence of unmeasured confounding. . .was expected given that we did not control for several potential confounders that may impact $PM_{2.5}$-mortality associations, such as smoking, socio-economic status (SES), gaseous pollutants, $PM_{2.5}$ components, and long-term time trends in $PM_{2.5}$'' and that ''spatial confounding may bias mortality risks both towards and away from the null'' (Docket ID EPA–HQ–OAR–2015–0072–0065; accessible in *https://www.regulations.gov/*).

copollutant confounding, and provide additional information on the shape of the C–R curve. As evaluated in the 2019 ISA, experimental and epidemiologic evidence for cardiovascular effects, and respiratory effects to a more limited degree, supports the plausibility of mortality due to long-term $PM_{2.5}$ exposures. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-term $PM_{2.5}$ exposure and mortality, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.4).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship exists between short-term exposure to $PM_{2.5}$ and mortality'' (U.S. EPA, 2009a). This conclusion was based on the evaluation of both multi- and single-city epidemiologic studies that consistently reported positive associations between short-term $PM_{2.5}$ exposure and non-accidental mortality. These associations were strongest, in terms of magnitude and precision, primarily at lags of 0 to 1 days. Examination of the potential confounding effects of gaseous copollutants was limited, though evidence from single-city studies indicated that gaseous copollutants have minimal effect on the $PM_{2.5}$-mortality relationship (*i.e.,* associations remain robust to inclusion of other pollutants in copollutant models). The evaluation of cause-specific mortality found that effect estimates were larger in magnitude, but also had larger confidence intervals, for respiratory mortality compared to cardiovascular mortality. Although the largest mortality risk estimates were for respiratory mortality, the interpretation of the results was complicated by the limited coherence from studies of respiratory morbidity. However, the evidence from studies of cardiovascular morbidity provided both coherence and biological plausibility for the relationship between short-term $PM_{2.5}$ exposure and cardiovascular mortality.

Multicity studies evaluated in the 2019 ISA and the ISA Supplement provide evidence of primarily positive associations between daily $PM_{2.5}$ exposures and mortality, with percent increases in total mortality ranging from 0.19% (Lippmann et al., 2013) to 2.80% (Kloog et al., 2013) [55] at lags of 0 to 1 days in single-pollutant models. Whereas many studies assign exposures using data from ambient monitors, other studies employ hybrid modeling approaches, which estimate $PM_{2.5}$ concentrations using data from a variety of sources (*i.e.,* from satellites, land use information, and modeling, in addition to monitors) and enable the inclusion of less urban and more rural locations in analyses (*e.g.,* Kloog et al., 2013, Lee et al., 2015, Shi et al., 2016).

Some studies have expanded the examination of potential confounders including long-term temporal trends, weather, and co-occurring pollutants. Mortality associations were found to remain positive, although in some cases were attenuated, when using different approaches to account for temporal trends or weather covariates (*e.g.,* U.S. EPA, 2019a, section 11.1.5.1). For example, Sacks et al. (2012) examined the influence of model specification using the approaches for confounder adjustment from models employed in several multicity studies within the context of a common data set (U.S. EPA, 2019a, section 11.1.5.1). These models use different approaches to control for long-term temporal trends and the potential confounding effects of weather. The authors report that associations between daily $PM_{2.5}$ and cardiovascular mortality were similar across models, with the percent increase in mortality ranging from 1.5–2.0% (U.S. EPA, 2019a, Figure 11–4). Thus, alternative approaches to controlling for long-term temporal trends and for the potential confounding effects of weather may influence the magnitude of the association between $PM_{2.5}$ exposures and mortality but have not been found to influence the direction of the observed association (U.S. EPA, 2019a, section 11.1.5.1). Taken together, the 2019 ISA and the ISA Supplement conclude that recent multicity studies conducted in the U.S., Canada, Europe, and Asia continue to provide consistent evidence of positive associations between short-term $PM_{2.5}$ exposures and total mortality across studies that use different approaches to control for the potential confounding effects of weather (*e.g.,* temperature) (U.S. EPA, 2019a, section 1.4.1.5.1; U.S. EPA, 2022a, section 3.2.1.2).

With regard to copollutants, studies evaluated in the 2019 ISA provide additional evidence that associations between short-term $PM_{2.5}$ exposures and mortality remain positive and relatively unchanged in copollutant models with both gaseous pollutants and $PM_{10–2.5}$ (U.S. EPA, 2019a, section 11.1.4). Additionally, the low ($r < 0.4$) to moderate correlations ($r = 0.4–0.7$) between $PM_{2.5}$ and gaseous pollutants and $PM_{10–2.5}$ increase the confidence in $PM_{2.5}$ having an independent effect on mortality (U.S. EPA, 2019a, section 11.1.4). Consistent with the studies evaluated in the 2019 ISA, studies evaluated in the ISA Supplement that used data from more recent years also indicate that associations between short-term $PM_{2.5}$ exposure and mortality remain unchanged in copollutant models. However, the evidence indicates that the association could be larger in magnitude in the presence of some copollutants such as oxidant gases (Lavigne et al., 2018; Shin et al., 2021).

The generally positive associations reported with mortality are supported by a small group of studies employing alternative methods for confounder control or quasi-experimental statistical approaches (U.S. EPA, 2019a, section 11.1.2.1). For example, two studies by Schwartz et al. report associations between $PM_{2.5}$ instrumental variables and mortality (U.S. EPA, 2019a, Table 11–2), including in an analysis limited to days with 24-hour average $PM_{2.5}$ concentrations $<30\ \mu g/m^3$ (Schwartz et al., 2015; Schwartz et al., 2017). In addition to the main analyses, these studies conducted Granger-like causality tests as sensitivity analyses to examine whether there was evidence of an association between mortality and $PM_{2.5}$ after the day of death, which would support the possibility that unmeasured confounders were not accounted for in the statistical model. Neither study reports evidence of an association with $PM_{2.5}$ after death (*i.e.,* they do not indicate unmeasured confounding). Yorifuji et al. (2016) conducted a quasi-experimental study to examine whether a specific regulatory action in Tokyo, Japan (*i.e.,* a diesel emission control ordinance) resulted in a subsequent reduction in daily mortality (Yorifuji et al., 2016). The authors reported a reduction in mortality in Tokyo due to the ordinance, compared to Osaka, which did not have a similar diesel emission control ordinance in place. In another study, Schwartz et al. (2018) utilized three statistical methods including instrumental variable analysis, a negative exposure control, and marginal structural models to estimate the association between $PM_{2.5}$ and daily mortality (Schwartz et al., 2018). Results from this study continue to support a relationship between short-term $PM_{2.5}$ exposure and mortality. Additional epidemiologic studies evaluated in the ISA Supplement that employed alternative methods for confounder control to examine the association between short-term $PM_{2.5}$ exposure and

[55] As detailed in the Preface to the ISA, risk estimates are for a 10 $\mu g/m^3$ increase in 24-hour avg $PM_{2.5}$ concentrations, unless otherwise noted (U.S. EPA, 2019a).

mortality also report consistent positive associations in studies that examine effects across multiple cities in the U.S. (U.S. EPA, 2022a).

The positive associations for total mortality reported across the majority of studies evaluated are further supported by cause-specific mortality analyses, which generally report consistent, positive associations with both cardiovascular and respiratory mortality (U.S. EPA, 2019a, section 11.1.3). Recent multicity studies evaluated in the ISA Supplement add to the body of evidence indicating a relationship between short-term $PM_{2.5}$ exposure and cause-specific mortality, with more variability in the magnitude and precision of associations for respiratory mortality (U.S. EPA, 2022a; Figure 3–14). For both cardiovascular and respiratory mortality, there has been a limited assessment of potential copollutant confounding, though initial evidence indicates that associations remain positive and relatively unchanged in models with gaseous pollutants and $PM_{10–2.5}$, which further supports the copollutant analyses conducted for total mortality. The strong evidence for ischemic events and heart failure, as detailed in the assessment of cardiovascular morbidity (U.S. EPA, 2019a, Chapter 6), provides biological plausibility for $PM_{2.5}$-related cardiovascular mortality, which comprises the largest percentage of total mortality (*i.e.,* ~33%) (NHLBI, 2017). Although there is evidence for exacerbations of COPD and asthma, the collective body of respiratory morbidity evidence provides limited biological plausibility for $PM_{2.5}$-related respiratory mortality (U.S. EPA, 2019a, Chapter 5).

In the 2009 ISA, one of the main uncertainties identified was the regional and city-to-city heterogeneity in $PM_{2.5}$-mortality associations. Studies evaluated in the 2019 ISA examine both city-specific as well as regional characteristics to identify the underlying contextual factors that could contribute to this heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Analyses focusing on effect modification of the $PM_{2.5}$ mortality relationship by $PM_{2.5}$ components, regional patterns in $PM_{2.5}$ components and city specific differences in composition and sources indicate some differences in the $PM_{2.5}$ composition and sources across cities and regions, but these differences do not fully explain the observed heterogeneity. Additional studies find that factors related to potential exposure differences, such as housing stock and commuting, as well as city specific factors (*e.g.,* land use, port volume, and traffic information), may also explain some of the observed heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Collectively, studies evaluated in the 2019 ISA and the ISA Supplement indicate that the heterogeneity in $PM_{2.5}$ mortality risk estimates cannot be attributed to one factor, but instead a combination of factors including, but not limited to, PM composition and sources as well as community characteristics that could influence exposures (U.S. EPA, 2019a, section 11.1.12; U.S. EPA, 2022a, section 3.2.1.2.1).

A number of studies evaluated in the 2019 ISA and ISA Supplement conducted systematic evaluations of the lag structure of associations for the $PM_{2.5}$-mortality relationship by examining either a series of single day or multiday lags and these studies continue to support an immediate effect (*i.e.,* lag 0 to 1 days) of short-term $PM_{2.5}$ exposures on mortality (U.S. EPA, 2019a, section 11.1.8.1; U.S. EPA, 2022a, section 3.2.1.1). Recent studies also conducted analyses comparing the traditional 24-hour average exposure metric with a subdaily metric (*i.e.,* 1-hour max) and provide evidence of a similar pattern of associations for both the 24-hour average and 1-hour max metric, with the association larger in magnitude for the 24-hour average metric.

Multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term (24-hour average $PM_{2.5}$ concentrations) $PM_{2.5}$ exposures below 35 μg/m³ (Lee et al., 2015),[56] below 30 μg/m³ (Shi et al., 2016), and below 25 μg/m³ (Di et al., 2017a), indicating that risks associated with short-term $PM_{2.5}$ exposures are not disproportionately driven by the peaks of the air quality distribution. Additional studies examined the shape of the C–R relationship for short-term $PM_{2.5}$ exposure and mortality and whether a threshold exists below which mortality effects do not occur (U.S. EPA, 2019a, section 11.1.10). These studies used various statistical approaches and consistently demonstrate linear C–R relationships with no evidence of a threshold.

Moreover, recent studies evaluated in the ISA Supplement provide additional support for a linear, no-threshold C–R relationship between short-term $PM_{2.5}$ exposure and mortality, with confidence in the shape decreasing at concentrations below 5 μg/m³ (Shi et al., 2016; Lavigne et al., 2018). Recent analyses provide initial evidence indicating that $PM_{2.5}$-mortality associations persist and may be stronger (*i.e.,* a steeper slope) at lower concentrations (*e.g.,* Di et al., 2017a; Figure 11–12 in U.S. EPA, 2019). However, given the limited data available at the lower end of the distribution of ambient $PM_{2.5}$ concentrations, the shape of the C–R curve remains uncertain at these low concentrations. Although difficulties remain in assessing the shape of the short-term $PM_{2.5}$-mortality C–R relationship, to date, studies have not conducted systematic evaluations of alternatives to linearity and recent studies evaluated in the ISA Supplement continue to provide evidence of a no-threshold linear relationship, with less confidence at concentrations lower than 5 μg/m³.

Overall, epidemiologic studies evaluated in the 2019 ISA and the ISA Supplement build upon and extend the conclusions of the 2009 ISA for the relationship between short-term $PM_{2.5}$ exposures and total mortality. Supporting evidence for $PM_{2.5}$-related cardiovascular morbidity, and more limited evidence from respiratory morbidity, provide biological plausibility for mortality due to short-term $PM_{2.5}$ exposures. The primarily positive associations observed across studies conducted in diverse geographic locations is further supported by the results from copollutant analyses indicating robust associations, along with evidence from analyses examining the C–R relationship. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term $PM_{2.5}$ exposure and mortality, which is further supported by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.1.4, p. 3–69).

ii. Cardiovascular Effects

Long-Term $PM_{2.5}$ Exposures

The scientific evidence reviewed in the 2009 ISA was ''sufficient to infer a causal relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2009a). The strongest line of evidence comprised findings from several large epidemiologic studies of U.S. and Canadian cohorts that reported consistent positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (Pope et al., 2004; Krewski et al., 2009; Miller et al.,

[56] Lee et al. (2015) restrict exposures below 35 μg/m³ only in areas with annual average concentrations <12 μg/m³. Additionally, Lee et al. (2015) also report that positive and statistically significant associations between short-term $PM_{2.5}$ exposures and mortality persist in analyses restricted to areas with long-term concentrations below 12 μg/m³.

2007; Laden et al., 2006). Studies of long-term $PM_{2.5}$ exposure and cardiovascular morbidity were limited in number. Biological plausibility and coherence with the epidemiologic findings were provided by studies using genetic mouse models of atherosclerosis demonstrating enhanced atherosclerotic plaque development and inflammation, as well as changes in measures of impaired heart function, following 4- to 6-month exposures to $PM_{2.5}$ concentrated ambient particles (CAPs), and by a limited number of studies reporting CAPs-induced effects on coagulation factors, vascular reactivity, and worsening of experimentally induced hypertension in mice (U.S. EPA, 2009a).

Consistent with the evidence assessed in the 2009 ISA, the 2019 ISA concludes that recent studies, together with the evidence available in previous reviews, support a causal relationship between long-term exposure to $PM_{2.5}$ and cardiovascular effects. Additionally, recent epidemiologic studies published since the completion of the 2019 ISA and evaluated in the ISA Supplement expands the body of evidence and further supports such a conclusion (U.S. EPA, 2022a). As discussed above (section II.A.2.a.i), results from U.S. and Canadian cohort studies evaluated in the 2019 ISA conducted at varying spatial and temporal scales and employing a variety of exposure assessment and statistical methods consistently report positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019, Figure 6–19, section 6.2.10). Positive associations between long-term $PM_{2.5}$ exposures and cardiovascular mortality are generally robust in copollutant models adjusted for ozone, NO_2, $PM_{10–2.5}$, or SO_2. In addition, most of the results from analyses examining the shape of the C–R relationship between long-term $PM_{2.5}$ exposures and cardiovascular mortality support a linear relationship and do not identify a threshold below which mortality effects do not occur (U.S. EPA, 2019a, section 6.2.16, Table 6–52).

The body of literature examining the relationship between long-term $PM_{2.5}$ exposure and cardiovascular morbidity has greatly expanded since the 2009 ISA, with positive associations reported in several cohorts evaluated in the 2019 ISA (U.S. EPA, 2019a, section 6.2). Though results for cardiovascular morbidity are less consistent than those for cardiovascular mortality (U.S. EPA, 2019a, section 6.2), studies in the 2019 ISA and the ISA Supplement provide some evidence for associations between long-term $PM_{2.5}$ exposures and the progression of cardiovascular disease. Positive associations with cardiovascular morbidity (*e.g.,* coronary heart disease, stroke, arrhythmias, myocardial infarction (MI), atherosclerosis progression) are observed in several epidemiologic studies (U.S. EPA, 2019a, sections 6.2.2 to 6.2.9; U.S. EPA, 2022a, section 3.1.2.2). Additionally, studies evaluated in the ISA Supplement report positive associations among those with pre-existing conditions, among patients followed after a cardiac event procedure, and among those with a first hospital admission for heart attacks among older adults enrolled in Medicare (U.S. EPA, 2022a, sections 3.1.1 and 3.1.2).

Recent studies published since the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement further assessed the relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects by conducting accountability analyses or by using alternative methods for confounder control in evaluating the association between long-term $PM_{2.5}$ exposure and cardiovascular hospital admissions (U.S. EPA, 2022a, section 3.1.2.3). Studies that apply alternative methods for confounder control increase confidence in the relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects by using methods that reduce uncertainties related to potential confounding through statistical and/or study design approaches. For example, to control for potential confounding Wei et al. (2021) used a doubly robust additive model (DRAM) and found an association between long-term exposure to $PM_{2.5}$ and cardiovascular effects, including MI, stoke, and atrial fibrillation, among the Medicare population. For example, an accountability study by Henneman et al. (2019) utilized a difference-in-difference (DID) approach to determine the relationship between coal-fueled power plant emissions and cardiovascular effects and found that reductions in $PM_{2.5}$ concentrations resulted in reductions of cardiovascular-related hospital admissions. Furthermore, several recent epidemiologic studies evaluated in the ISA Supplement reported that the association between long-term $PM_{2.5}$ exposure with stroke persisted after adjustment for NO_2 but was attenuated in the model with O_3 and oxidant gases represented by the redox weighted average of NO_2 and O_3 (U.S. EPA, 2022a, section 3.1.2.2.8). Overall, these studies report consistent findings that long-term $PM_{2.5}$ exposure is related to increased hospital admissions for a variety of cardiovascular disease outcomes among large nationally representative cohorts and provide additional support for a relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects.

Positive associations reported in epidemiologic studies are supported by toxicological evidence evaluated in the 2019 ISA. The positive associations reported in epidemiologic studies are supported by toxicological evidence for increased plaque progression in mice following long-term exposure to $PM_{2.5}$ collected from multiple locations across the U.S. (U.S. EPA, 2019a, section 6.2.4.2). A small number of epidemiologic studies also report positive associations between long-term $PM_{2.5}$ exposure and heart failure, changes in blood pressure, and hypertension (U.S. EPA, 2019a, sections 6.2.5 and 6.2.7). Associations with heart failure are supported by animal toxicological studies demonstrating decreased cardiac contractility and function, and increased coronary artery wall thickness following long-term $PM_{2.5}$ exposure (U.S. EPA, 2019a, section 6.2.5.2). Similarly, a limited number of animal toxicological studies demonstrating a relationship between long-term $PM_{2.5}$ exposure and consistent increases in blood pressure in rats and mice are coherent with epidemiologic studies reporting positive associations between long-term exposure to $PM_{2.5}$ and hypertension.

Additionally, a number of studies evaluated in the ISA Supplement focusing on morbidity outcomes, including those that focused on incidence of MI, atrial fibrillation (AF), stroke, and congestive heart failure (CHF), expand the evidence pertaining to the shape of the C–R relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects. These studies use statistical techniques that allow for departures from linearity (U.S. EPA, 2022a, Table 3–3), and generally support the evidence characterized in the 2019 ISA showing linear, no-threshold C–R relationship for most cardiovascular disease (CVD) outcomes. However, there is evidence for a sublinear or supralinear C–R relationship for some outcomes (U.S. EPA, 2022a, section 3.1.2.2.9).[57]

Longitudinal epidemiologic analyses also report positive associations with markers of systemic inflammation (U.S. EPA, 2019a, section 6.2.11), coagulation (U.S. EPA, 2019a, section 6.2.12), and

[57] As noted above for mortality, uncertainty in the shape of the C–R relationship increases near the upper and lower ends of the distribution due to limited data.

endothelial dysfunction (U.S. EPA, 2019a, section 6.2.13). These results are coherent with animal toxicological studies generally reporting increased markers of systemic inflammation, oxidative stress, and endothelial dysfunction (U.S. EPA, 2019a, section 6.2.12.2 and 6.2.14).

In summary, the 2019 ISA concludes that there is consistent evidence from multiple epidemiologic studies illustrating that long-term exposure to $PM_{2.5}$ is associated with mortality from cardiovascular causes. Epidemiologic studies evaluated in the ISA Supplement provide additional evidence of positive associations between long-term $PM_{2.5}$ exposure and cardiovascular morbidity (U.S. EPA, 2022a, section 3.1.2.2). Associations with coronary heart disease (CHD), stroke and atherosclerosis progression were observed in several additional epidemiologic studies, providing coherence with the mortality findings. Results from copollutant models generally support an independent effect of $PM_{2.5}$ exposure on mortality. Additional evidence of the independent effect of $PM_{2.5}$ on the cardiovascular system is provided by experimental studies in animals, which support the biological plausibility of pathways by which long-term exposure to $PM_{2.5}$ could potentially result in outcomes such as CHD, stroke, CHF, and cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.2.2).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship exists between short-term exposure to $PM_{2.5}$ and cardiovascular effects'' (U.S. EPA, 2009a). The strongest evidence in the 2009 ISA was from epidemiologic studies of emergency department (ED) visits and hospital admissions for IHD and heart failure (HF), with supporting evidence from epidemiologic studies of cardiovascular mortality (U.S. EPA, 2009a). Animal toxicological studies provided coherence and biological plausibility for the positive associations reported with MI, ED visits, and hospital admissions. These included studies reporting reduced myocardial blood flow during ischemia and studies indicating altered vascular reactivity. In addition, effects of $PM_{2.5}$ exposure on a potential indicator of ischemia (*i.e.,* ST segment depression on an electrocardiogram) were reported in both animal toxicological and epidemiologic panel studies.[58] Key uncertainties from the last review resulted from inconsistent results across disciplines with respect to the relationship between short-term exposure to $PM_{2.5}$ and changes in blood pressure, blood coagulation markers, and markers of systemic inflammation. In addition, while the 2009 ISA identified a growing body of evidence from controlled human exposure and animal toxicological studies, uncertainties remained with respect to biological plausibility.

Studies evaluated in the 2019 ISA provide additional support for a causal relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. This includes generally positive associations observed in multicity epidemiologic studies of emergency department visits and hospital admissions for IHD, heart failure (HF), and combined cardiovascular-related endpoints. In particular, nationwide studies of older adults (65 years and older) using Medicare records report positive associations between $PM_{2.5}$ exposures and hospital admissions for HF (U.S. EPA, 2019a, section 6.1.3.1). Moreover, recent multicity studies, published after the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement, are consistent with studies evaluated in the 2019 ISA that report positive association between short-term $PM_{2.5}$ exposure and ED visits and hospital admission for IHD, heart attacks, and HF (U.S. EPA, 2022a, section 3.1). Epidemiologic studies conducted in single cities contribute some support to the causality determination, though associations reported in single-city studies are less consistently positive than in multicity studies, and include a number of studies reporting null associations (U.S. EPA, 2019a, sections 6.1.2 and 6.1.3). As a whole, though, the recent body of IHD and HF epidemiologic evidence supports the evidence from previous ISAs reporting mainly positive associations between short-term $PM_{2.5}$ concentrations and emergency department visits and hospital admissions.

Consistent with the evidence assessed in the 2019 ISA, some studies evaluated in the ISA Supplement report no evidence of an association with stroke, regardless of stroke subtype. Additionally, as in the 2019 ISA, evidence evaluated in the ISA Supplement continues to indicate an immediate effect of $PM_{2.5}$ on cardiovascular-related outcomes primarily within the first few days after exposure, and that associations generally persisted in models adjusted for copollutants (U.S. EPA, 2022a, section 3.1.1.2).

The ISA Supplement includes additional epidemiologic studies, published since the literature cutoff date for the 2019 ISA, including accountability analyses and epidemiologic studies that employ alternative methods for confounder control to evaluate the association between short-term $PM_{2.5}$ exposure and cardiovascular-related effects (U.S. EPA, 2022a, section 3.1.1.3). These studies employ a number of statistical approaches and report positive associations, providing additional support for a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects, while also reducing uncertainties related to potential confounder bias.

A number of controlled human exposure, animal toxicological, and epidemiologic panel studies provide evidence that $PM_{2.5}$ exposure could plausibly result in IHD or HF through pathways that include endothelial dysfunction, arterial thrombosis, and arrhythmia (U.S. EPA, 2019a, section 6.1.1). The most consistent evidence from recent controlled human exposure studies is for endothelial dysfunction, as measured by changes in brachial artery diameter or flow mediated dilation. Multiple controlled human exposure studies that examined the potential for endothelial dysfunction report an effect of $PM_{2.5}$ exposure on measures of blood flow (U.S. EPA, 2019a, section 6.1.13.2). However, these studies report variable results regarding the timing of the effect and the mechanism by which reduced blood flow occurs (*i.e.,* availability vs sensitivity to nitric oxide). In addition, some controlled human exposure studies using CAPs report evidence for small increases in blood pressure (U.S. EPA, 2019a, section 6.1.6.3). Although not entirely consistent, there is also some evidence across controlled human exposure studies for conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (HRV) (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). A recent study by Wyatt et al.

[58] Some animal studies included in the 2009 ISA examined exposures to mixtures, such as motor vehicle exhaust or woodsmoke. In these studies, it was unclear if the resulting cardiovascular effects could be attributed specifically to the fine particle component of the mixture.

(2020), evaluated in the ISA Supplement, adds to the limited evidence base of controlled human exposure studies conducted at near ambient $PM_{2.5}$ concentrations. The study, completed in healthy young adults subject to intermittent exercise, found some significant cardiovascular effects (*e.g.,* systematic inflammation markers, including C-reactive protein (CRP), and cardiac repolarization). Thus, when taken as a whole, controlled human exposure studies are coherent with epidemiologic studies in that they demonstrate that short-term exposures to $PM_{2.5}$ may result in the types of cardiovascular endpoints that could lead to emergency department visits and hospital admissions for IHD or HF, as well as mortality in some people.

Animal toxicological studies published since the 2009 ISA and evaluated in the 2019 ISA also support a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. A study demonstrating decreased cardiac contractility and left ventricular pressure in mice is coherent with the results of epidemiologic studies that report associations between short-term $PM_{2.5}$ exposure and heart failure (U.S. EPA, 2019a, section 6.1.3.3). In addition, and as with controlled human exposure studies, there is generally consistent evidence in animal toxicological studies for indicators of endothelial dysfunction (U.S. EPA, 2019a, section 6.1.13.3). Some studies in animals also provide evidence for changes in a number of other cardiovascular endpoints following short-term $PM_{2.5}$ exposure including conduction abnormalities and arrhythmia (U.S. EPA, 2019a, section 6.1.4.4), changes in HRV (U.S. EPA, 2019a, section 6.1.10.3), changes in blood pressure (U.S. EPA, 2019a, section 6.1.6.4), and evidence for systemic inflammation and oxidative stress (U.S. EPA, 2019a, section 6.1.11.3).

In summary, evidence evaluated in the 2019 ISA extends the consistency and coherence of the evidence base evaluated in the 2009 ISA and prior assessments. Epidemiologic studies reporting robust associations in copollutant models are supported by direct evidence from controlled human exposure and animal toxicologic studies reporting independent effects of $PM_{2.5}$ exposures on endothelial dysfunction as well as endpoints indicating impaired cardiac function, increased risk of arrhythmia, changes in HRV, increases in BP, and increases in indicators of systemic inflammation, oxidative stress, and coagulation (U.S. EPA, 2019, section 6.1.16). For some cardiovascular effects, there are inconsistencies in results across some animal toxicological, controlled human exposure, and epidemiologic panel studies, though this may be due to substantial differences in study design and/or study populations. Overall, the results from epidemiologic panel, controlled human exposure, and animal toxicological studies, in particular those related to endothelial dysfunction, impaired cardiac function, ST segment depression, thrombosis, conduction abnormalities, and changes in blood pressure provide coherence and biological plausibility for the consistent results from epidemiologic studies observing positive associations between short-term $PM_{2.5}$ exposures and IHD and HF, and ultimately cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.1.4).

iii. Respiratory Effects

Long-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2009a). This conclusion was based mainly on epidemiologic evidence demonstrating associations between long-term $PM_{2.5}$ exposure and changes in lung function or lung function growth in children. Biological plausibility was provided by a single animal toxicological study examining pre- and post-natal exposure to $PM_{2.5}$ CAPs, which found impaired lung development. Epidemiologic evidence for associations between long-term $PM_{2.5}$ exposure and other respiratory outcomes, such as the development of asthma, allergic disease, and COPD; respiratory infection; and the severity of disease was limited, both in the number of studies available and the consistency of the results. Experimental evidence for other outcomes was also limited, with one animal toxicological study reporting that long-term exposure to $PM_{2.5}$ CAPs results in morphological changes in nasal airways of healthy animals. Other animal studies examined exposure to mixtures, such as motor vehicle exhaust and woodsmoke, and effects were not attributed specifically to the particulate components of the mixture.

Cohort studies evaluated in the 2019 ISA provided additional support for the relationship between long-term $PM_{2.5}$ exposure and decrements in lung function growth (as a measure of lung development), indicating a robust and consistent association across study locations, exposure assessment methods, and time periods (U.S. EPA, 2019a, section 5.2.13). This relationship was further supported by a retrospective study that reports an association between declining $PM_{2.5}$ concentrations and improvements in lung function growth in children (U.S. EPA, 2019a, section 5.2.11). Epidemiologic studies also examine asthma development in children (U.S. EPA, 2019a, section 5.2.3), with prospective cohort studies reporting generally positive associations, though several are imprecise (*i.e.,* they report wide confidence intervals). Supporting evidence is provided by studies reporting associations with asthma prevalence in children, with childhood wheeze, and with exhaled nitric oxide, a marker of pulmonary inflammation (U.S. EPA, 2019a, section 5.2.13). Additionally, the 2019 ISA includes an animal toxicological study showing the development of an allergic phenotype and an increase in a marker of airway responsiveness supports the biological plausibility of the development of allergic asthma (U.S. EPA, 2019a, section 5.2.13). Other epidemiologic studies report a $PM_{2.5}$-related acceleration of lung function decline in adults, while improvement in lung function was observed with declining $PM_{2.5}$ concentrations (U.S. EPA, 2019a, section 5.2.11). A longitudinal study found declining $PM_{2.5}$ concentrations are also associated with an improvement in chronic bronchitis symptoms in children, strengthening evidence reported in the 2009 ISA for a relationship between increased chronic bronchitis symptoms and long-term $PM_{2.5}$ exposure (U.S. EPA, 2019a, section 5.2.11). A common uncertainty across the epidemiologic evidence is the lack of examination of copollutants to assess the potential for confounding. While there is some evidence that associations remain robust in models with gaseous pollutants, a number of these studies examining copollutant confounding were conducted in Asia, and thus have limited generalizability due to high annual pollutant concentrations.

When taken together, the 2019 ISA concludes that the epidemiologic evidence strongly supports a relationship with decrements in lung function growth asthma development in children, as well as increased bronchitis symptoms in children with asthma. Additionally, the epidemiologic

evidence strongly supports a relationship with an acceleration of lung function decline in adults, and with respiratory mortality and cause-specific respiratory mortality for COPD and respiratory infection (U.S. EPA, 2019a, p. 1–34). In support of the biological plausibility of associations reported in epidemiologic studies associated with respiratory health effects, animal toxicological studies evaluated in the 2019 ISA continue to provide direct evidence that long-term exposure to $PM_{2.5}$ results in a variety of respiratory effects, including pulmonary oxidative stress, inflammation, and morphologic changes in the upper (nasal) and lower airways. Other results show that changes are consistent with the development of allergy and asthma, and with impaired lung development. Overall, the 2019 ISA concludes that ''the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019a, section 5.2.13).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA (U.S. EPA, 2009a) concluded that a ''causal relationship is likely to exist'' between short-term $PM_{2.5}$ exposure and respiratory effects. This conclusion was based mainly on the epidemiologic evidence demonstrating positive associations with various respiratory effects. Specifically, the 2009 ISA described epidemiologic evidence as consistently showing $PM_{2.5}$-associated increases in hospital admissions and ED visits for COPD and respiratory infection among adults or people of all ages, as well as increases in respiratory mortality. These results were supported by studies reporting associations with increased respiratory symptoms and decreases in lung function in children with asthma, though the epidemiologic evidence was inconsistent for hospital admissions or emergency department visits for asthma. Studies examining copollutant models showed that $PM_{2.5}$ associations with respiratory effects were robust to inclusion of CO or SO_2 in the model, but often were attenuated (though still positive) with inclusion of O_3 or NO_2. In addition to the copollutant models, evidence supporting an independent effect of $PM_{2.5}$ exposure on the respiratory system was provided by animal toxicological studies of $PM_{2.5}$ CAPs demonstrating changes in some pulmonary function parameters, as well as inflammation, oxidative stress, injury, enhanced allergic responses, and reduced host defenses. Many of these effects have been implicated in the pathophysiology for asthma exacerbation, COPD exacerbation, or respiratory infection. In the few controlled human exposure studies conducted in individuals with asthma or COPD, $PM_{2.5}$ exposure mostly had no effect on respiratory symptoms, lung function, or pulmonary inflammation. Available studies in healthy people also did not clearly demonstrate respiratory effects following short-term $PM_{2.5}$ exposures.

Epidemiologic studies evaluated in the 2019 ISA continue to provide strong evidence for a relationship between short-term $PM_{2.5}$ exposure and several respiratory-related endpoints, including asthma exacerbation (U.S. EPA, 2019a, section 5.1.2.1), COPD exacerbation (U.S. EPA, 2019a, section 5.1.4.1), and combined respiratory-related diseases (U.S. EPA, 2019a, section 5.1.6), particularly from studies examining ED visits and hospital admissions. The generally positive associations between short-term $PM_{2.5}$ exposure and asthma and COPD as well as ED visits and hospital admissions are supported by epidemiologic studies demonstrating associations with other respiratory-related effects such as symptoms and medication use that are indicative of asthma and COPD exacerbations (U.S. EPA, 2019a, sections 5.1.2.2 and 5.4.1.2). The collective body of epidemiologic evidence for asthma exacerbation is more consistent in children than in adults. Additionally, epidemiologic studies examining the relationship between short-term $PM_{2.5}$ exposure and respiratory mortality provide evidence of consistent positive associations, demonstrating a continuum of effects (U.S. EPA, 2019a, section 5.1.9).

Epidemiologic studies evaluated in the 2019 ISA expand the assessment of potential copollutant confounding evaluated in the 2009 ISA. There is some evidence that $PM_{2.5}$ associations with asthma exacerbation, combined respiratory-related diseases, and respiratory mortality remain relatively unchanged in copollutant models with gaseous pollutants including O_3, NO_2, SO_2, and with more limited evidence for CO, as well as other particle sizes (*i.e.,* $PM_{10-2.5}$) (U.S. EPA, 2019a, section 5.1.10.1).

Insight into whether there is an independent effect of $PM_{2.5}$ on respiratory health is also partially addressed by findings from animal toxicological studies evaluated in the 2019 ISA. Specifically, short-term exposure to $PM_{2.5}$ enhanced asthma-related responses in an animal model of allergic airways disease and enhanced lung injury and inflammation in an animal model of COPD (U.S. EPA, 2019a, sections 5.1.2.4.4 and 5.1.4.4.3). The experimental evidence provides biological plausibility for some respiratory-related endpoints, including limited evidence of altered host defense and greater susceptibility to bacterial infection as well as consistent evidence of respiratory irritant effects. However, animal toxicological evidence for other respiratory effects is inconsistent. A recent study evaluated in the ISA supplement by Wyatt et al. (2020) and conducted at near ambient $PM_{2.5}$ concentrations, adds to the limited evidence base of controlled human exposure studies. The study, completed in healthy young adults subject to intermittent exercise, found some significant respiratory effects (including decrease in lung function), however these findings were inconsistent with the controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, section 5.1.7.2, 5.1.2.3, and 6.1.11.2.1).

The 2019 ISA concludes that ''[t]he strongest evidence of an effect of short-term $PM_{2.5}$ exposure on respiratory effects is provided by epidemiologic studies of asthma and COPD exacerbation. While animal toxicological studies provide biological plausibility for these findings, some uncertainty remains with respect to the independence of $PM_{2.5}$ effects'' (U.S. EPA, 2019a, p. 5–155). When taken together, the 2019 ISA concludes that this evidence ''is sufficient to conclude that a causal relationship is likely to exist between short-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019a, p. 5–155).

iv. Cancer

The 2009 ISA concluded that the overall body of evidence was ''suggestive of a causal relationship between relevant $PM_{2.5}$ exposures and cancer'' (U.S. EPA, 2009a). This conclusion was based primarily on positive associations observed in a limited number of epidemiologic studies of lung cancer mortality. The few epidemiologic studies that had evaluated $PM_{2.5}$ exposure and lung cancer incidence or cancers of other organs and systems generally did not show evidence of an association. Toxicological studies did not focus on exposures to specific PM size fractions, but rather investigated the effects of exposures to total ambient PM, or other source-based PM such as wood smoke. Collectively, results of in vitro studies were consistent with the larger body of evidence demonstrating that ambient PM and PM from specific combustion sources are mutagenic and genotoxic. However, animal inhalation studies

found little evidence of tumor formation in response to chronic exposures. A small number of studies provided preliminary evidence that PM exposure can lead to changes in methylation of DNA, which may contribute to biological events related to cancer.

Since the completion of the 2009 ISA, additional cohort studies provide evidence that long-term $PM_{2.5}$ exposure is positively associated with lung cancer mortality and with lung cancer incidence, and provide initial evidence for an association with reduced cancer survival (U.S. EPA, 2019a, section 10.2.5). Re-analyses of the ACS cohort using different years of $PM_{2.5}$ data and follow up, along with various exposure assignment approaches, provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposure and lung cancer mortality (U.S. EPA, 2019a, Figure 10–3). Additional support for positive associations with lung cancer mortality is provided by recent epidemiologic studies using individual level data to control for smoking status, as well as by studies of people who have never smoked (though such studies generally report wide confidence intervals due to the small number of lung cancer mortality cases within this population), and in additional analyses of cohorts that relied upon proxy measures to account for smoking status (U.S. EPA, 2019a, section 10.2.5.1.1). Although studies that evaluate lung cancer incidence, including studies of people who have never smoked, are limited in number, studies in the 2019 ISA generally report positive associations with long-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 10.2.5.1.2). A subset of the studies focusing on lung cancer incidence also examined histological subtype, providing some evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019a, section 10.2.5.1.2). Associations between long-term $PM_{2.5}$ exposure and lung cancer incidence were found to remain relatively unchanged, though in some cases confidence intervals widened, in analyses that attempted to reduce exposure measurement error by accounting for length of time at residential address or by examining different exposure assignment approaches (U.S. EPA, 2019a, section 10.2.5.1.2).

To date, relatively few studies have evaluated the potential for copollutant confounding of the relationship between long-term $PM_{2.5}$ exposure and lung cancer mortality or incidence. A small number of such studies have generally focused on O_3 and report that $PM_{2.5}$ associations remain relatively unchanged in copollutant models (U.S. EPA, 2019a, section 10.2.5.1.3). However, available studies have not systematically evaluated the potential for copollutant confounding by other gaseous pollutants or by other particle size fractions (U.S. EPA, 2019a, section 10.2.5.1.3).

Compared to total (non-accidental) mortality (U.S. EPA, 2019a, section 10.2.4.1.4), fewer studies have examined the shape of the C–R curve for cause-specific mortality outcomes, including lung cancer. Several studies of lung cancer mortality and incidence have reported no evidence of deviations from linearity in the shape of the C–R relationship (Lepeule et al., 2012; Raaschou-Nielsen et al., 2013; Puett et al., 2014), though authors provided only limited discussions of results (U.S. EPA, 2019a, section 10.2.5.1.4).

In support of the biological plausibility of an independent effect of $PM_{2.5}$ on lung cancer, the 2019 ISA notes evidence from experimental and epidemiologic studies demonstrating that $PM_{2.5}$ exposure can lead to a range of effects indicative of mutagenicity, genotoxicity, and carcinogenicity, as well as epigenetic effects (U.S. EPA, 2019a, section 10.2.7). For example, both in vitro and in vivo toxicological studies have shown that $PM_{2.5}$ exposure can result in DNA damage (U.S. EPA, 2019a, section 10.2.2). Although such effects do not necessarily equate to carcinogenicity, the evidence that PM exposure can damage DNA, and elicit mutations, provides support for the plausibility of epidemiologic associations exhibited with lung cancer mortality and incidence. Additional supporting studies indicate the occurrence of micronuclei formation and chromosomal abnormalities (U.S. EPA, 2019a, section 10.2.2.3), and differential expression of genes that may be relevant to cancer pathogenesis, following $PM_{2.5}$ exposures. Experimental and epidemiologic studies that examine epigenetic effects indicate changes in DNA methylation, providing some support that $PM_{2.5}$ exposure contributes to genomic instability (U.S. EPA, 2019a, section 10.2.3). Overall, there is limited evidence that long-term $PM_{2.5}$ exposure is associated with cancers in other organ systems, though there is some evidence that $PM_{2.5}$ exposure may reduce survival in individuals with cancer (U.S. EPA, 2019a, section 10.2.7; U.S. EPA, 2022a, section 2.1.1.4.1).

Epidemiologic evidence for associations between $PM_{2.5}$ and lung cancer mortality and incidence, together with evidence supporting the biological plausibility of such associations, contributes to the 2019 ISA's conclusion that the evidence ''is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and cancer'' (U.S. EPA, 2019, section 10.2.7).

v. Nervous System Effects

Reflecting the very limited evidence available in the 2012 review, the 2009 ISA did not make a causality determination for long-term $PM_{2.5}$ exposures and nervous system effects (U.S. EPA, 2009c). Since the 2012 review, this body of evidence has grown substantially (U.S. EPA, 2019, section 8.2). Animal toxicological studies assessed in in the 2019 ISA report that long-term $PM_{2.5}$ exposures can lead to morphologic changes in the hippocampus and to impaired learning and memory. This evidence is consistent with epidemiologic studies reporting that long-term $PM_{2.5}$ exposure is associated with reduced cognitive function (U.S. EPA, 2019a, section 8.2.5). Further, while the evidence is limited, the presence of early markers of Alzheimer's disease pathology has been demonstrated in rodents following long-term exposure to $PM_{2.5}$ CAPs. These findings support reported associations with neurodegenerative changes in the brain (*i.e.,* decreased brain volume), all-cause dementia, or hospitalization for Alzheimer's disease in a small number of epidemiologic studies (U.S. EPA, 2019a, section 8.2.6). Additionally, loss of dopaminergic neurons in the substantia nigra, a hallmark of Parkinson disease, has been reported in mice (U.S. EPA, 2019a, section 8.2.4), though epidemiologic studies provide only limited support for associations with Parkinson's disease (U.S. EPA, 2019a, section 8.2.6). Overall, the lack of consideration of copollutant confounding introduces some uncertainty in the interpretation of epidemiologic studies of nervous system effects, but this uncertainty is partly addressed by the evidence for an independent effect of $PM_{2.5}$ exposures provided by experimental animal studies.

While the findings described above are most relevant to older adults, several studies of neurodevelopmental effects in children have also been conducted. Epidemiologic studies provided limited evidence of an association between $PM_{2.5}$ exposure during pregnancy and childhood on cognitive and motor development (U.S. EPA, 2019, section 8.2.5.2). While some studies report positive associations between long-term

exposure to $PM_{2.5}$ during the prenatal period and autism spectrum disorder (ASD) (U.S. EPA, 2019, section 8.2.7.2), the interpretation of these epidemiologic studies is limited due to the small number of studies, their lack of control for potential confounding by copollutants, and uncertainty related to the critical exposure windows. Biological plausibility is provided for the ASD findings by a study in mice that found inflammatory and morphologic changes in the corpus collosum and hippocampus, as well as ventriculomegaly (*i.e.,* enlarged lateral ventricles) in young mice following prenatal exposure to $PM_{2.5}$ CAPs.

Taken together, the 2019 ISA concludes that studies indicate long-term $PM_{2.5}$ exposures can lead to effects on the brain associated with neurodegeneration (*i.e.,* neuroinflammation and reductions in brain volume), as well as cognitive effects in older adults (U.S. EPA, 2019a, Table 1–2). Animal toxicological studies provide evidence for a range of nervous system effects in adult animals, including neuroinflammation and oxidative stress, neurodegeneration, cognitive effects, and effects on neurodevelopment in young animals. The epidemiologic evidence is more limited, but studies generally support associations between long-term $PM_{2.5}$ exposure and changes in brain morphology, cognitive decrements and dementia. There is also initial, and limited, evidence for neurodevelopmental effects, particularly ASD. The consistency and coherence of the evidence supports the 2019 ISA's conclusion that ''the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and nervous system effects'' (U.S. EPA, 2019a, section 8.2.9).

vi. Other Effects

For other health effect categories that were evaluated for their relationship with $PM_{2.5}$ exposures (*i.e.,* short-term $PM_{2.5}$ exposure and nervous system effects and short- and long-term $PM_{2.5}$ exposure and metabolic effects, reproduction and fertility, and pregnancy and birth outcomes (U.S. EPA, 2022a, Table ES–1), the currently available evidence is ''suggestive of, but not sufficient to infer, a causal relationship,'' mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, the potential for confounding, and potential modes of action (U.S. EPA, 2019a, sections 7.14, 7.2.10, 8.1.6, and 9.1.5). The causality determination for short-term $PM_{2.5}$ exposure and nervous system effects in the 2019 ISA reflects a revision to the causality determination in the 2009 ISA from ''inadequate to infer a causal relationship,'' while this is the first-time assessments of causality were conducted for long-term $PM_{2.5}$ exposure and nervous system effects, as well as short- and long-term $PM_{2.5}$ exposure and metabolic effects reflect.

Recent studies evaluated in the 2019 ISA also further explored the relationship between short-and long-term UFP exposure and health effects. (*i.e.,* cardiovascular effects and short-term UFP exposures; respiratory effects and short-term UFP exposures; and nervous system effects and long- and short-term exposures (U.S. EPA, 2022a, Table ES–1). The currently available evidence is ''suggestive of, but not sufficient to infer, a causal relationship'' for short-term UFP exposure and cardiovascular and respiratory effects and for short- and long-term UFP exposure and nervous system effects, primarily due to uncertainties and limitations in the evidence, specifically, variability across studies in the definition of UFPs and the exposure metric used (U.S. EPA, 2019a, P.3.1; U.S. EPA, 2022a, section 3.3.1.6.3). The causality determinations for the other health effect categories evaluated in the 2019 ISA are ''inadequate to infer a causal relationship.'' Additionally, this is the first time assessments of causality were conducted for short- and long-term UFP exposure and metabolic effects and long-term UFP exposure and nervous system effects (U.S. EPA, 2022a, Table ES–1).

With the advent of the global COVID–19 pandemic, a number of recent studies evaluated in the ISA Supplement examined the relationship between ambient air pollution, specifically $PM_{2.5}$, and SARS–CoV–2 infections and COVID–19 deaths, including a few studies within the U.S. and Canada (U.S. EPA, 2022a, section 3.3.2).[59] Some studies examined whether daily changes in $PM_{2.5}$ can influence SARS–CoV–2 infection and COVID–19 death (U.S. EPA, 2022a, section 3.3.2.1). Additionally, several studies evaluated whether long-term $PM_{2.5}$ exposure increases the risk of SARS–CoV–2 infection and COVID–19 death in North America (U.S. EPA, 2022a, section 3.3.2.2). While there is initial evidence of positive associations with SARS–CoV–2 infection and COVID–19 death, uncertainties remain due to methodological issues that may influence the results, including: (1) The use of ecological study design; (2) studies were conducted during the ongoing pandemic when the etiology of COVID–19 was still not well understood (*e.g.,* specifically, there are important differences in COVID–19-related outcomes by a variety of factors such as race and SES); and (3) studies did not account for crucial factors that could influence results (*e.g.,* stay-at-home orders, social distancing, use of masks, and testing capacity) (U.S. EPA, 2022a, chapter 5). Taken together, while there is initial evidence of positive associations with SARS–CoV–2 infection and COVID–19 death, uncertainties remain due to methodological issues.

b. Public Health Implications and At-Risk Populations

The public health implications of the evidence regarding $PM_{2.5}$-related health effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Such factors are discussed below in the context of our consideration of the health effects evidence related to $PM_{2.5}$ in ambient air. This section also summarizes the current information on population groups at increased risk of the effects of $PM_{2.5}$ in ambient air.

The information available in this reconsideration has not altered our understanding of human populations at risk of health effects from $PM_{2.5}$ exposures. As recognized in the 2020 review, the 2019 ISA cites extensive evidence indicating that ''both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects'' (U.S. EPA, 2019a, p. 12–1). Factors that may contribute to increased risk of $PM_{2.5}$-related health effects include lifestage (children and older adults), pre-existing diseases (cardiovascular disease and

[59] While there is no exact corollary within the 2019 ISA for these types of studies, the 2019 ISA presented evidence that evaluates the potential relationship between short- and long-term $PM_{2.5}$ exposure and respiratory infection (U.S. EPA, 2022a, section 5.1.5 and 5.2.6). Studies assessed in the 2019 ISA report some evidence of positive associations between short-term $PM_{2.5}$ and hospital admissions and ED visits for respiratory infections, however the interpretation of these studies is complicated by the variability in the type of respiratory infection outcome examined (U.S. EPA, 2022a, Figure 5–7). In the 2019 ISA, studies of long-term $PM_{2.5}$ exposure were limited and while there were some positive associations reported, there was minimal overlap in respiratory infection outcomes examined across studies. Exposure to $PM_{2.5}$ has been shown to impair host defense, specifically altering macrophage function, providing a biological pathway by which $PM_{2.5}$ exposure could lead to respiratory infection (U.S. EPA, 2022a, sections 5.1.1 and 5.1.5.) There is some additional evidence that $PM_{2.5}$ exposure can lead to decreases in an individual's immune response, which can subsequently facilitate replication of respiratory viruses (Bourdrel et al., 2021).

respiratory disease), race/ethnicity, and SES.[60]

Children make up a substantial fraction of the U.S. population, and often have unique factors that contribute to their increased risk of experiencing a health effect due to exposures to ambient air pollutants because of their continuous growth and development.[61] Children may be particularly at risk for health effects related to ambient $PM_{2.5}$ exposures compared with adults because they have (1) a developing respiratory system, (2) increased ventilation rates relative to body mass compared with adults, and (3) an increased proportion of oral breathing, particularly in boys, relative to adults (U.S. EPA, 2019a, section 12.5.1.1). There is strong evidence that demonstrates $PM_{2.5}$ associated health effects in children, particularly from epidemiologic studies of long-term $PM_{2.5}$ exposure and impaired lung function growth, decrements in lung function, and asthma development. However, there is limited evidence from stratified analyses that children are at increased risk of $PM_{2.5}$-related health effects compared to adults. Additionally, there is some evidence that indicates that children receive higher $PM_{2.5}$ exposures than adults, and dosimetric differences in children compared to adults can contribute to higher doses (U.S. EPA, 2019a, section 12.5.1.1).

In the U.S., older adults, often defined as adults 65 years of age and older, represent an increasing portion of the population and often have pre-existing diseases or conditions that may compromise biological function. While there is limited evidence to indicate that older adults have higher exposures than younger adults, older adults may receive higher doses of $PM_{2.5}$ due to dosimetric differences. There is consistent evidence from studies of older adults demonstrating generally consistent positive associations in studies examining health effects from short- and long-term $PM_{2.5}$ exposure and cardiovascular or respiratory hospital admissions, emergency department visits, or mortality (U.S. EPA, 2019a, sections 6.1, 6.2, 11.1, 11.2, 12.5.1.2). Additionally, several animal toxicological, controlled human exposure, and epidemiologic studies did not stratify results by lifestage, but instead focused the analyses on older individuals, and can provide coherence and biological plausibility for the occurrence among this lifestage (U.S. EPA, 2019a, section 12.5.1.2).

Individuals with pre-existing disease may be considered at greater risk of an air pollution-related health effect than those without disease because they are likely in a compromised biological state that can vary depending on the disease and severity. With regard to cardiovascular disease, we first note that cardiovascular disease is the leading cause of death in the U.S., accounting for one in four deaths, and approximately 12% of the adult population in the U.S. has a cardiovascular disease (U.S. EPA, 2019a, section 12.3.1). Strong evidence demonstrates that there is a causal relationship between cardiovascular effects and long- and short-term exposures to $PM_{2.5}$. Some of the evidence supporting this conclusion is from studies of panels or cohorts with pre-existing cardiovascular disease, which provide supporting evidence but do not directly demonstrate an increased risk (U.S. EPA, 2019a, section 12.3.1). Epidemiologic evidence indicates that individuals with pre-existing cardiovascular disease may be at increased risk for $PM_{2.5}$-associated health effects compared to those without pre-existing cardiovascular disease. While the evidence does not consistently support increased risk for all pre-existing cardiovascular diseases, there is evidence that certain pre-existing cardiovascular diseases (*e.g.,* hypertension) may be a factor that increases $PM_{2.5}$-related risk. Furthermore, there is strong evidence supporting a causal relationship for long- and short-term $PM_{2.5}$ exposure and cardiovascular effects, particularly for IHD (U.S. EPA, 2019a, chapter 6, section 12.3.1).

With regard to respiratory disease, we first note that the most chronic respiratory diseases in the U.S. are asthma and COPD. Asthma affects a substantial fraction of the U.S. population and is the leading chronic disease among children. COPD primarily affects older adults and contributes to compromised respiratory function and underlying pulmonary inflammation. The body of evidence indicates that individuals with pre-existing respiratory diseases, particularly asthma and COPD, may be at increased risk for $PM_{2.5}$-related health effects compared to those without pre-existing respiratory diseases (U.S. EPA, 2019a, section 12.3.5). There is strong evidence indicating $PM_{2.5}$-associated respiratory effects among those with asthma, which forms the primary evidence base for the likely to be causal relationship between short-term exposures to $PM_{2.5}$ and respiratory health effects (U.S. EPA, 2019a, section 12.3.5). For asthma, epidemiologic evidence demonstrates associations between short-term $PM_{2.5}$ exposures and respiratory effects, particularly evidence for asthma exacerbation, and controlled human exposure and animal toxicological studies demonstrate support for the biological plausibility for asthma exacerbation with $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 12.3.5.1). For COPD, epidemiologic studies report positive associations between short-term $PM_{2.5}$ exposures and hospital admissions and emergency department visits for COPD, with supporting evidence from panel studies demonstration COPD exacerbation. Epidemiologic evidence is supported by some experimental evidence of COPD-related effects, which provides support for the biological plausibility for COPD in response to $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 12.3.5.2).

There is strong evidence for racial and ethnic disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk, as assessed in the 2019 ISA and with even more evidence available since the literature cutoff date for the 2019 ISA and evaluated in the ISA Supplement. There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations (U.S. EPA, 2019a, Figure 12–2; U.S. EPA, 2022a, Figure 3–38). Black populations or individuals that live in predominantly Black neighborhoods experience higher $PM_{2.5}$ exposures, in comparison to non-Hispanic White populations. There is also consistent evidence across multiple studies that demonstrate increased risk of $PM_{2.5}$-related health effects, with the strongest evidence for health risk disparities for mortality (U.S. EPA, 2019a, section 12.5.4). There is also evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations for cause-specific mortality and incident hypertension (U.S. EPA, 2022a, section 3.3.3.2).

Socioeconomic status (SES) is a composite measure that includes metrics such as income, occupation, or education, and can play a role in access to healthy environments as well as access to healthcare. SES may be a factor that contributes to differential risk from $PM_{2.5}$-related health effects. Studies assessed in the 2019 ISA and ISA Supplement provide evidence that lower SES communities are exposed to higher concentrations of $PM_{2.5}$

[60] As described in the 2019 ISA, other factors that have the potential to contribute to increased risk include obesity, diabetes, genetic factors, smoking status, sex, diet, and residential location (U.S. EPA, 2019, chapter 12).

[61] Children, as used throughout this document, generally refers to those younger than 18 years old.

compared to higher SES communities (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022a, section 3.3.3.1.1). Studies using composite measures of neighborhood SES consistently demonstrated a disparity in both $PM_{2.5}$ exposure and the risk of $PM_{2.5}$-related health outcomes. There is some evidence that supports associations larger in magnitude between mortality and long-term $PM_{2.5}$ exposures for those with low income or living in lower income areas compared to those with higher income or living in higher income neighborhoods (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022a, section 3.3.3.1.1). Additionally, evidence supports conclusions that lower SES is associated with cause-specific mortality and certain health endpoints (*i.e.,* HI and CHF), but less so for all-cause or total (non-accidental) mortality (U.S. EPA, 2022a, section 3.3.3.1).

The magnitude and characterization of a public health impact is dependent upon the size and characteristics of the populations affected, as well as the type or severity of the effects. As summarized above, lifestage (children and older adults), race/ethnicity and SES are factors that increase the risk of $PM_{2.5}$-related health effects. The American Community Survey (ACS) for 2019 estimates that approximately 22% and 16% of the U.S. population are children (age<18) and older adults (age 65+), respectively. For all ages, non-Hispanic Black and Hispanic populations comprise approximately 12% and 18% of the overall U.S. population in 2019. Currently available information that helps to characterize key features of these population is included in the 2022 PA (U.S. EPA, 2022b, Table 3–2).

As noted above, individuals with pre-existing cardiovascular disease and pre-existing respiratory disease may also be at increased risk of $PM_{2.5}$-related health effects. Currently available information that helps to characterize key features of populations with cardiovascular or respiratory diseases or conditions is included in the 2022 PA (U.S. EPA, 2022b, Table 3–3). The National Center for Health Statistics data for 2018 indicate that, for adult populations, older adults (*e.g.,* those 65 years and older) have a higher prevalence of cardiovascular diseases compared to younger adults (*e.g.,* those 64 years and younger). For respiratory diseases, older adults also have a higher prevalence of emphysema than younger adults, and adults 44 years or older have a higher prevalence of chronic bronchitis. However, the prevalence for asthma is generally similar across all adult age groups.

With respect to race, American Indians or Alaskan Native populations have the highest prevalence of all heart disease and coronary heart disease, while Black populations have the highest prevalence of hypertension and stroke. Hypertension has the highest prevalence across all racial groups compared to other cardiovascular diseases or conditions, ranging from approximately 22% to 32% of each racial group. Overall, the prevalence of cardiovascular diseases or conditions is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. Asthma prevalence is highest among Black and American Indian or Alaska Native populations, while the prevalence of chronic bronchitis and emphysema is generally similar across racial groups. Overall, the prevalence of respiratory diseases is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. With regard to ethnicity, cardiovascular and respiratory disease prevalence across all diseases or conditions is generally similar between Hispanic and non-Hispanic populations, although non-Hispanics have a slightly higher prevalence compared to Hispanics.

Taken together, this information indicates that the groups at increased risk of $PM_{2.5}$-related health effects represent a substantial portion of the total U.S. population. In evaluating the primary $PM_{2.5}$ standards, an important consideration is the potential $PM_{2.5}$-related public health impacts in these populations.

c. $PM_{2.5}$ Concentrations in Key Studies Reporting Health Effects

To inform conclusions on the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards, the sections below summarize the 2022 PA's evaluation of the $PM_{2.5}$ exposures, specifically the concentrations that have been examined in controlled human exposure studies, animal toxicological studies, and epidemiologic studies. The 2022 PA places the greatest emphasis on the health outcomes for which the 2019 ISA concludes that the evidence supports a ''causal'' or a ''likely to be causal'' relationship with short- or long-term $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.3.3). As described in greater detail in section II.A.2 above, this includes short- or long-term $PM_{2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects and long-term $PM_{2.5}$ exposures and cancer and nervous system effects. While the causality determinations in the 2019 ISA are informed by studies evaluating a wide range of $PM_{2.5}$ concentrations,[62] the sections below summarize the considerations in the 2022 PA regarding the degree to which the evidence assessed in the 2019 ISA and ISA Supplement supports the occurrence of PM-related health effects at concentrations relevant to informing conclusions on the primary $PM_{2.5}$ standards. In so doing, the 2022 PA focuses on the available studies that are most directly informative to reaching conclusions regarding the adequacy of the current primary $PM_{2.5}$ standards (*e.g.,* epidemiologic studies with annual mean $PM_{2.5}$ concentrations near or below the level of the standard; and controlled human exposure studies at $PM_{2.5}$ exposures that elicit consistent effects, as well as examining $PM_{2.5}$ exposures at concentrations that are at or near the level of the standard).

i. $PM_{2.5}$ Exposure Concentrations Evaluated in Experimental Studies

Evidence for a particular $PM_{2.5}$-related health outcome is strengthened when results from experimental studies demonstrate biologically plausible mechanisms through which adverse human health outcomes could occur (U.S. EPA, 2015, p. 20). Two types of experimental studies are of particular importance in understanding the effects

[62] As described in more detail in section 5 of the Preamble to the ISAs, judgments regarding causality take into consideration a number of aspects when evaluating the available scientific evidence (U.S. EPA, 2015, Table I). In reaching conclusions regarding causality, ''evidence is evaluated for major outcome categories or groups of related endpoints (*e.g.,* respiratory effects, vegetation growth), integrating evidence from across disciplines, and evaluating the coherence of evidence across a spectrum of related endpoints'' (U.S. EPA, 2015, p. 24). Furthermore, ''[i]n drawing judgments regarding causality for the criteria air pollutants, the ISA focuses on evidence of effects in the range of relevant pollutant exposures or doses and not on determination of causality at any dose. Emphasis is placed on evidence of effects at doses (*e.g.,* blood Pb concentration) or exposures (*e.g.,* air concentrations) that are relevant to, or somewhat above, those currently experienced by the population. The extent to which studies of higher concentrations are considered varies by pollutant and major outcome category, but generally includes those with doses or exposures in the range of one to two orders of magnitude above current or ambient conditions to account for intra-species variability and toxicokinetic or toxicodynamic differences between experimental animals and humans. Studies that use higher doses or exposures may also be considered to the extent that they provide useful information to inform understanding of mode of action, inter-species differences, or factors that may increase risk of effects for a population and if biological mechanisms have not been demonstrated to differ based on exposure concentration. Thus, a causality determination is based on weight-of-evidence evaluation for health or welfare effects, focusing on the evidence from exposures or doses generally ranging from recent ambient concentrations to one or two orders of magnitude above recent ambient concentrations'' (U.S. EPA, 2015, p. 24).

of PM exposures: controlled human exposure and animal toxicological studies. In such studies, investigators expose human volunteers or laboratory animals, respectively, to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels. Thus, controlled human exposure and animal toxicological studies can provide information on the health effects of experimentally administered pollutant exposures under highly controlled laboratory conditions (U.S. EPA, 2015, p. 11).

Controlled human exposure studies have reported that $PM_{2.5}$ exposures lasting from less than one hour up to five hours can impact cardiovascular function,[63] and the most consistent evidence from these studies is for impaired vascular function (U.S. EPA, 2019a, section 6.1.13.2). In addition, although less consistent, the 2019 ISA notes that studies examining $PM_{2.5}$ exposures also provide evidence for increased blood pressure (U.S. EPA, 2019a, section 6.1.6.3), conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). The 2019 ISA concludes that, when taken as a whole, controlled human exposure studies demonstrate that short-term exposure to $PM_{2.5}$ may impact cardiovascular function in ways that could lead to more serious outcomes (U.S. EPA, 2019a, section 6.1.16). Thus, such studies can provide insight into the potential for specific $PM_{2.5}$ exposures to result in physiological changes that could increase the risk of more serious effects. Table 3–4 in the 2022 PA summarizes information from the 2019 ISA and 2022 ISA supplement on available controlled human exposure studies that evaluate effects on markers of cardiovascular function following exposure to $PM_{2.5}$ (U.S. EPA, 2022b). Most of the controlled human exposure studies in Table 3–4 of the 2022 PA have evaluated average $PM_{2.5}$ concentrations at or above about 100 μg/m^3, with exposure durations typically up to about two hours. Statistically significant effects on one or more indicators of cardiovascular function are often, though not always, reported following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 μg/m^3, with less consistent evidence for effects following exposures to concentrations lower than 120 μg/m^3. Impaired vascular function, the effect identified in the 2019 ISA as the most consistent across studies (U.S. EPA, 2019a, section 6.1.13.2) is shown following 2-hour exposures to $PM_{2.5}$ concentrations at and above 149 μg/m^3. Mixed results are reported in the studies that evaluated longer exposure durations (*i.e.,* longer than 2 hours) and lower (*i.e.,* near-ambient) $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.3.3.1). For example, significant effects for some outcomes were reported following 5-hour exposures to 24 μg/m^3 in Hemmingsen et al. (2015b), but not for other outcomes following 5-hour exposures to 24 μg/m^3 in Hemmingsen et al. (2015a) and not following 24-hour exposures to 10.5 μg/m^3 in Bräuner et al. (2008). Additionally, Wyatt et al. (2020) found significant effects for some cardiovascular (*e.g.,* systematic inflammation markers, cardiac repolarization, and decreased pulmonary function) effects following 4-hour exposures to 37.8 μg/m^3 in healthy young participants (18–35 years, n=21) who were subject to intermittent moderate exercise. The higher ventilation rate and longer exposure duration in this study compared to most controlled human exposure studies is roughly equivalent to a 2-hour exposure of 75–100 μg/m^3 of $PM_{2.5}$. Therefore, dosimetric considerations may explain the observed changes in inflammation in young healthy individuals. Though this study provides evidence of some effects at lower $PM_{2.5}$ concentrations, overall, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, sections 5.1.7., 5.1.2.3.3, and 6.1.11.2.1; U.S. EPA, 2022a, section 3.3.1).

While controlled human exposure studies are important in establishing biological plausibility, it is unclear how the results from these studies alone and the importance of the effects observed in these studies, should be interpreted with respect to adversity to public health. More specifically, impaired vascular function can signal an intermediate effect along the potential biological pathways for cardiovascular effects following short-term exposure to $PM_{2.5}$ and show a role for exposure to $PM_{2.5}$ leading to potential worsening of IHD and heart failure followed potentially by ED visits, hospital admissions, or mortality (U.S. EPA, 2019a, section 6.1 and Figure 6–1). However, just observing the occurrence of impaired vascular function alone does not clearly suggest an adverse health outcome. Additionally, associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), which cooperatively updated the ATS 2000 statement *What Constitutes an Adverse Health Effect of Air Pollution* (ATS, 2000) with new scientific findings, including the evidence related to air pollution and the cardiovascular system (Thurston et al., 2017).[64] With regard to vascular function, the ATS/ERS statement considers the adversity of both chronic and acute reductions in endothelial function. While the ATS/ERS statement concluded that chronic endothelial and vascular dysfunction can be judged to be a biomarker of an adverse health effect from air pollution, they also conclude that ''the health relevance of acute reductions in endothelial function induced by air pollution is less certain'' (Thurston et al., 2017). This is particularly informative to our consideration of the controlled human exposure studies which are short-term in nature (*i.e.,* generally ranging from 2- to 5-hours), including those studies that are conducted at near-ambient $PM_{2.5}$ concentrations.

The 2022 PA also notes that it is important to recognize that controlled human exposure studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects.

[63] In contrast, controlled human exposure studies provide little evidence for respiratory effects following short-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 5.1, Table 5–18). Therefore, this section focuses on cardiovascular effects evaluated in controlled human exposure studies of $PM_{2.5}$ exposure.

[64] The ATS/ERS described its 2017 statement as one ''intended to provide guidance to policymakers, clinicians and public health professionals, as well as others who interpret the scientific evidence on the health effects of air pollution for risk management purposes'' and further notes that ''considerations as to what constitutes an adverse health effect, in order to provide guidance to researchers and policymakers when new health effects markers or health outcome associations might be reported in future.'' The most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer ''strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,'' providing a general framework for interpreting evidence that proposes a ''set of considerations that can be applied in forming judgments'' for this context (Thurston et al., 2017).

These studies, therefore, often do not include children, older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations.

Nonetheless, to provide some insight into what these controlled human exposure studies may indicate regarding short-term exposure to peak $PM_{2.5}$ concentrations and how concentrations relate to ambient $PM_{2.5}$ concentrations, analyses in the 2022 PA (U.S. EPA, 2022b, Figure 2–19) examine monitored 2-hour $PM_{2.5}$ concentrations (the exposure window most often utilized in the controlled human exposure studies) at sites meeting the current primary $PM_{2.5}$ standards to evaluate the degree to which 2-hour ambient $PM_{2.5}$ concentrations at such locations are likely to exceed the 2-hour exposure concentrations in the controlled human exposure studies at which statistically significant effects are reported in multiple studies for one or more indicators of cardiovascular function. At sites meeting the current primary $PM_{2.5}$ standards, most 2-hour concentrations are below 10 $\mu g/m^3$, and almost never exceed 30 $\mu g/m^3$. The extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations is shifted higher during the warmer months (April to September), generally corresponding to the period of peak wildfire frequency in the U.S. At sites meeting the current primary $PM_{2.5}$ standards, the highest 2-hour concentrations measured tend to occur during the period of peak wildfire frequency (*i.e.,* 99.9th percentile of 2-hour concentrations is 62 $\mu g/m^3$ during the warm season considered as a whole). Most of the sites measuring these very high concentrations are in the northwestern U.S. and California (U.S. EPA, 2022b, Appendix A, Figure A–1), where wildfires have been relatively common in recent years. When the typical fire season is excluded from the analysis, the extreme upper end of the distribution is reduced (*i.e.,* 99.9th percentile of 2-hour concentrations is 55 $\mu g/m^3$).[65] Given these results, the 2022 PA concludes that $PM_{2.5}$ exposure concentrations evaluated in most of these controlled human exposure studies are well-above the 2-hour ambient $PM_{2.5}$ concentrations typically measured in locations meeting the current primary standards.

With respect to animal toxicological studies, the 2019 ISA relies on animal toxicological studies to support the plausibility of a wide range of $PM_{2.5}$-related health effects. While animal toxicological studies often examine more severe health outcomes and longer exposure durations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects, to human populations. The 2022 PA considers these uncertainties when evaluating what the available animal toxicological studies may indicate with regard to the current primary $PM_{2.5}$ standards.

As with controlled human exposure studies, most animal toxicological studies evaluated in the 2019 ISA have examined effects following exposure to $PM_{2.5}$ well above the concentrations likely to be allowed by the current $PM_{2.5}$ standards. Such studies have generally examined short-term exposures to $PM_{2.5}$ concentrations ranging from 100 to >1,000 $\mu g/m^3$ and long-term exposures to concentrations from 66 to >400 $\mu g/m^3$ (*e.g.,* see U.S. EPA, 2019a, Table 1–2). Two exceptions are animal toxicological studies reporting impaired lung development following long-term exposures (*i.e.,* 24 hours per day for several months prenatally and postnatally) to an average $PM_{2.5}$ concentration of 16.8 $\mu g/m^3$ (Mauad et al., 2008) and increased carcinogenic potential following long-term exposures (*i.e.,* 2 months) to an average $PM_{2.5}$ concentration of 17.7 $\mu g/m^3$ (Cangerana Pereira et al., 2011). These two studies report serious effects following long-term exposures to $PM_{2.5}$ concentrations similar to the ambient concentrations reported in some $PM_{2.5}$ epidemiologic studies (U.S. EPA, 2019a, Table 1–2), though still above the ambient concentrations likely to occur in areas meeting the current primary $PM_{2.5}$ standards. However, noting uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects to human populations, animal toxicological studies are of limited utility in informing decisions on the public health protection provided by the current or alternative primary $PM_{2.5}$ standards. Therefore, the animal toxicological studies are most useful in providing further evidence to support the biological mechanisms and plausibility of various adverse effects.

ii. Ambient $PM_{2.5}$ Concentrations in Locations of Epidemiologic Studies

As summarized in section II.A.2.a above, epidemiologic studies examining associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity represent a large part of the evidence base supporting several of the 2019 ISA's ''causal'' and ''likely to be causal'' determinations. The 2022 PA considers the ambient $PM_{2.5}$ concentrations present in areas where epidemiologic studies have evaluated associations with mortality or morbidity, and what such concentrations may indicate regarding the adequacy of the primary $PM_{2.5}$ standards. The use of information from epidemiologic studies to inform conclusions on the primary $PM_{2.5}$ standards is complicated by the fact that such studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, and do not identify the specific exposures that can lead to the reported effects. Rather, health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that $PM_{2.5}$-associated health effects do not occur. Therefore, the 2022 PA evaluates the $PM_{2.5}$ air quality distributions over which epidemiologic studies support health effect associations (U.S. EPA, 2022b, section 3.3.3.2). In the absence of discernible thresholds, the 2022 PA considers the study-reported ambient $PM_{2.5}$ concentrations reflecting estimated exposure with a focus around the middle portion of the $PM_{2.5}$ air quality distribution, where the bulk of the observed data reside and which provides the strongest support for reported health effect associations. The section below, as well as in more detail in section II.B.3.b.i of the proposal (88 FR 5594, January 27, 2023), describes the consideration of the key epidemiologic studies and observations from these studies, as evaluated in the 2022 PA (U.S. EPA, 2022b, section 3.3.3.2).

As an initial matter, in considering the $PM_{2.5}$ air quality distributions associated with mortality or morbidity in the key epidemiologic studies, the 2022 PA recognizes that in previous reviews, the decision framework used to judge adequacy of the existing $PM_{2.5}$ standards, and what levels of any potential alternative standards should be considered, placed significant weight on epidemiologic studies that assessed associations between $PM_{2.5}$ exposure and health outcomes that were most strongly supported by the body of scientific evidence. In doing so, the decision framework recognized that while there is no specific point in the air quality distribution of any

[65] Similar analyses of 4-hour and 5-hour $PM_{2.5}$ concentrations are presented in Appendix A, Figure A–2 and Figure A–3, respectively of the 2022 PA (U.S. EPA, 2022b).

epidemiologic study that represents a ''bright line'' at and above which effects have been observed and below which effects have not been observed, there is significantly greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to where the bulk of the health events in each study have been observed, generally at or around the mean concentration. This is the case both for studies of daily $PM_{2.5}$ exposures and for studies of annual average $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.3.3.2.1).

As discussed further in the 2022 PA, studies of daily $PM_{2.5}$ exposures examine associations between day-to-day variation in $PM_{2.5}$ concentrations and health outcomes, often over several years (U.S. EPA, 2022b, section 3.3.3.2.1). While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with ambient $PM_{2.5}$ concentrations around the middle of the air quality distributions examined (*i.e.,* ''typical'' days rather than days with extremely high or extremely low concentrations). Similarly, for studies of annual $PM_{2.5}$ exposures, most of the health events occur at estimated exposures that reflect annual average $PM_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Consistent with this, as noted in the 2022 PA (U.S. EPA, 2022b, section 3.3.1.1), several epidemiologic studies report that associations persist in analyses that exclude the upper portions of the distributions of estimated $PM_{2.5}$ exposures, indicating that ''peak'' $PM_{2.5}$ exposures are not disproportionately responsible for reported health effect associations.

Thus, in considering $PM_{2.5}$ air quality data from epidemiologic studies, consistent with approaches in the 2012 and 2020 reviews (78 FR 3161, January 15, 2013; U.S. EPA, 2011, sections 2.1.3 and 2.3.4.1; 85 FR 82716–82717, December 18, 2020; U.S. EPA, 2020b, sections 3.1.2 and 3.2.3), the 2022 PA evaluates study-reported means (or medians) of daily and annual average $PM_{2.5}$ concentrations as indicators for the middle portions of the air quality distributions, over which studies generally provide strong support for reported associations and for which confidence in the magnitude and significance of associations observed in the epidemiologic studies is greatest (78 FR 3101, January 15, 2013). In addition to the overall study means, the 2022 PA also focuses on concentrations somewhat below the means (*e.g.,* 25th and 10th percentiles), when such information is available from the epidemiologic studies, which again is consistent with approaches used in previous reviews. In so doing, the 2022 PA notes, as in previous reviews, that a relatively small portion of the health events are observed in the lower part of the air quality distribution and confidence in the magnitude and significance of the associations begins to decrease in the lower part of the air quality distribution. Furthermore, consistent with past reviews, there is no single percentile value within a given air quality distribution that is most appropriate or ''correct'' to use to characterize where our confidence in associations becomes appreciably lower. However, and as detailed further in the 2022 PA, the range from the 25th to 10th percentiles is a reasonable range to consider as a region where there is appreciably less confidence in the associations observed in epidemiologic studies compared to the means (U.S. EPA, 2022b, p. 3–69).[66]

In evaluating the overall study-reported means, and concentrations somewhat below the means from epidemiologic studies, the 2022 PA focuses on the form, averaging time and level of the current primary annual $PM_{2.5}$ standard. Consistent with the approaches used in the 2012 and 2020 reviews (78 FR 3161–3162, January 15, 2013; 85 FR 82716–82717, December 18, 2020), the annual standard has been utilized as the primary means of providing public health protection against the bulk of the distribution of short- and long-term $PM_{2.5}$ exposures. Thus, the evaluation of the study-reported mean concentrations from key epidemiologic studies lends itself best to evaluating the adequacy of the annual $PM_{2.5}$ standard (rather than the 24-hour standard with its 98th percentile form). This is true for the study-reported means from both long-term and short-term exposure epidemiologic studies, recognizing that the overall mean $PM_{2.5}$ concentrations reported in studies of short-term (24-hour) exposures reflect averages across the study population and over the years of the study. Thus, mean concentrations from short-term exposure studies reflect long-term averages of 24-hour $PM_{2.5}$ exposure estimates. In this manner, the examination of study-reported means in key epidemiologic studies in the 2022 PA aims to evaluate the protection provided by the annual $PM_{2.5}$ standard against the exposures where confidence is greatest for associations with mortality and morbidity. In addition, the protection provided by the annual standard is evaluated in conjunction with that provided by the 24-hour standard, with its 98th percentile form, which aims to provide supplemental protection against the short-term exposures to peak $PM_{2.5}$ concentrations that can occur in areas with strong contributions from local or seasonal sources, even when overall ambient mean $PM_{2.5}$ concentrations in an area remain relatively low.

In focusing on the annual standard, and in evaluating the range of study-reported exposure concentrations for which the strongest support for adverse health effects exists, the 2022 PA examines exposure concentrations in key epidemiologic studies to determine whether the current primary annual $PM_{2.5}$ standard provides adequate protection against these exposure concentrations. This means, as in past reviews, application of a decision framework based on assessing means reported in key epidemiologic studies must also consider how the study means were computed and how these values compare to the annual standard metric (including the level, averaging time and form) and the use of the monitor with the highest $PM_{2.5}$ design value in an area for compliance. In the 2012 review, it was recognized that the key epidemiologic studies computed the study mean using an average across monitor-based $PM_{2.5}$ concentrations. As such, the Agency noted that this decision framework applied an approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations. Further, the Agency included analyses (Hassett-Sipple et al., 2010; Frank, 2012) that examined the differences in these two metrics (*i.e.,* maximum monitor concentrations and composite monitor concentrations) across the U.S. and in areas included in the key epidemiologic studies and found that the maximum design value in an area was generally higher than the monitor average across that area, with the difference varying

[66] As detailed in the 2011 PA, we note the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which represents approximately 68% of normally distributed data, and in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011, p. 2–71; U.S. EPA, 2005, p. 5–22).

based on location and concentration. This information was taken into account in the Administrator's final decision in selecting a level for the primary annual $PM_{2.5}$ standard the 2012 review and discussed more specifically in her considerations on adequate margin of safety.

Consistent with the approach taken in 2012, in assessing how the overall mean (or median) $PM_{2.5}$ concentrations reported in key epidemiologic studies can inform conclusions on the primary annual $PM_{2.5}$ standard, the 2022 PA notes that the relationship between mean $PM_{2.5}$ concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative annual $PM_{2.5}$ standard levels in this reconsideration. In a given area, the area design value is based on the monitor in an area with the highest $PM_{2.5}$ concentrations and is used to determine compliance with the standard. The highest $PM_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and the distribution of $PM_{2.5}$ concentrations would generally be lower in other locations and at monitors in that area. As such, when an area is meeting a specific annual standard level, the annual average exposures in that area are expected to be at concentrations lower than that level and the average of the annual average exposures across that area are expected (*i.e.,* a metric similar to the study-reported mean values) to be lower than that level.[67]

Another important consideration is that there are a substantial number of different types of epidemiologic studies available since the 2012 review, included in both the 2019 ISA and the ISA Supplement, that make understanding the relationship between the mean $PM_{2.5}$ concentrations and the area design value even more important (U.S. EPA, 2019a; U.S. EPA, 2022a). While the key epidemiologic studies in the 2012 review were all monitor-based studies, the newer studies include hybrid modeling approaches, which have emerged in the epidemiologic literature as an alternative to approaches that only use ground-based monitors to estimate exposure. As assessed in the 2019 ISA and ISA Supplement, a substantial number of epidemiologic studies used hybrid model-based methods in evaluating associations between $PM_{2.5}$ exposure and health effects (U.S. EPA, 2019a; U.S. EPA, 2022a). Hybrid model-based studies employ various fusion techniques that combine ground-based monitored data with air quality modeled estimates and/or information from satellites to estimate $PM_{2.5}$ exposures.[68] Additionally, hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in so doing, tend to report lower mean $PM_{2.5}$ concentrations than monitor-based approaches because they include more suburban and rural areas where concentrations are lower. While these studies provide a broader estimation of $PM_{2.5}$ exposures compared to monitor-based studies (*i.e.,* $PM_{2.5}$ concentrations are estimated in areas without monitors), the hybrid modeling approaches result in study-reported means that are more difficult to relate to the annual standard metric and to the use of maximum monitor design values to assess compliance. In addition, and to further complicate the comparison, when looking across these studies, variations exist in how exposure is estimated between such studies, which in turn affects how the study means are calculated. Two important variations across studies include: (1) Variability in spatial scale used (*i.e.,* averages computed across the nation (or large portions of the country) versus a focus on only CBSAs) and (2) variability in exposure assignment methods (*i.e.,* averaging across all grid cells [non-population weighting], averaging across a scaled-up area like a ZIP code [aspects of population weighting applied], and/or applying population weighting). To elaborate further on the variability in exposure assignment methods, studies that use hybrid modeling approaches can estimate $PM_{2.5}$ concentrations at different spatial resolutions, including at 1 km x 1 km grid cells, at 12 km x 12 km grid cells, or at the census tract level. Mean reported $PM_{2.5}$ concentrations can then be estimated either by averaging up to a larger spatial resolution that corresponds to the spatial resolution for which health data exists (*e.g.,* ZIP code level) and therefore apply aspects of population weighting. These values are then averaged across all study locations at the larger spatial resolution (*e.g.,* averaged across all ZIP codes in the study) over the study period, resulting in the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. Other studies that use hybrid modeling methods to estimate $PM_{2.5}$ concentrations may use each grid cell to calculate the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. As such, these types of studies do not apply population weighting in their mean concentrations. In studies that use each grid cell to report a mean $PM_{2.5}$ concentration and do not apply aspects of population weighting, the study mean may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. The impact of the differences in methods is an important consideration when comparing mean concentrations across studies (U.S. EPA, 2022b, section 3.3.3.2.1). Thus, the 2022 PA also considers the methods used to estimate $PM_{2.5}$ concentrations, which vary from traditional methods using monitoring data from ground-based monitors[69] to those using more complex hybrid modeling approaches and how these methods calculate the study-reported mean $PM_{2.5}$ concentration.[70]

Given the emergence of the hybrid model-based epidemiologic studies since the 2012 review, the 2022 PA explores the relationship between the approaches used in these studies to estimate $PM_{2.5}$ concentrations and the impact that the different methods have on the study-reported mean $PM_{2.5}$ concentrations. The 2022 PA further seeks to understand how the approaches and resulting mean concentrations compare across studies, as well as what the resulting mean values represent relative to the annual standard. In so doing, the 2022 PA presents analyses that compare the area annual design values, composite monitor $PM_{2.5}$ concentrations, and mean concentrations from two hybrid modeling approaches, including evaluation of the means when population weighting is applied and when population weighting is not

[67] In setting a standard level that would require the design value monitor to meet a level equal to the study-reported mean $PM_{2.5}$ concentrations would generally result in lower concentrations of $PM_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where PM concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies.

[68] More detailed information about hybrid model methods and performance is described in section 2.3.3.2 of the 2022 PA (U.S. EPA, 2022b).

[69] In those studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ concentrations, approaches include: (1) $PM_{2.5}$ concentrations from a single monitor within a city/county; (2) average of $PM_{2.5}$ concentrations across all monitors within a city/county or other defined study area (*e.g.,* CBSA); or (3) population-weighted averages of exposures. Once the study location average $PM_{2.5}$ concentration is calculated, the study-reported long-term average is derived by averaging daily/annual $PM_{2.5}$ concentrations across all study locations over the entire study period.

[70] Detailed information on the methods by which mean $PM_{2.5}$ concentrations are calculated in key monitor- and hybrid model-based U.S. and Canadian epidemiologic studies are presented in Tables 3–6 through 3–9 in the 2022 PA (U.S. EPA, 2022b).

applied (U.S. EPA, 2022b, section 2.3.3.1).

In the air quality analyses comparing composite monitored $PM_{2.5}$ concentrations with annual $PM_{2.5}$ design values in U.S. CBSAs, maximum annual $PM_{2.5}$ design values were approximately 10% to 20% higher than annual average composite monitor concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (sections I.D.5.a above and U.S. EPA, 2022b, section 2.3.3.1, Figure 2–28 and Table 2–3). The difference between the maximum annual design value and average concentration in an area can be smaller or larger than this range (10–20%), depending on a variety of factors such as the number of monitors, monitor siting characteristics, the distribution of ambient $PM_{2.5}$ concentrations, and how the average concentrations are calculated (*i.e.,* averaged across monitors versus across modeled grid cells). Results of this analysis suggest that there will be a distribution of concentrations across an area and the maximum annual average monitored concentration in an area (at the design value monitor, used for compliance with the standard), will generally be 10–20% higher than the average $PM_{2.5}$ concentration across the other monitors in the area. Thus, in considering how the annual standard levels would relate to the study-reported means from key monitor-based epidemiologic studies, the 2022 PA generally concludes that an annual standard level that is no more than 10–20% higher than monitor-based study-reported mean $PM_{2.5}$ concentrations would generally maintain air quality exposures to be below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which the strongest support for adverse health effects occurring is available.

The 2022 PA also evaluates data from two hybrid modeling approaches (DI2019 and HA2020) that have been used in several recent epidemiologic studies (U.S. EPA, 2022b, section 2.3.3.2.4).[71] The analysis shows that the means differ when $PM_{2.5}$ concentrations are estimated in urban areas only (CBSAs) versus when the averages were calculated with all or most grid cells nationwide, likely because areas included outside of CBSAs tend to be more rural and have lower estimated $PM_{2.5}$ concentrations. The 2022 PA recognizes the importance of this variability in the means since the study areas included in the calculation of the mean, and more specifically whether a study is focused on nationwide, regional, or urban areas, will affect the calculation of the study mean based on how many rural areas, with lower estimated $PM_{2.5}$ concentrations, are included in the study area. While the determination of what spatial scale to use to estimate $PM_{2.5}$ concentrations does not inherently affect the quality of the epidemiologic study, the spatial scale can influence the calculated reported long-term mean concentration across the study area and period. The results of the analysis show that, regardless of the hybrid modeling approach assessed, the annual average $PM_{2.5}$ concentrations in CBSA-only analyses are 4–8% higher than for nationwide analyses, likely as a result of higher $PM_{2.5}$ concentrations in more densely populated areas, and exclusion of more rural areas (U.S. EPA, 2022b, Table 2–4). When evaluating comparisons between surfaces that estimate exposure using aspects of population weighting versus surfaces that do not calculate means using population weighting, surfaces that calculate long-term mean $PM_{2.5}$ concentrations with population-weighted averages have higher average annual $PM_{2.5}$ concentrations, compared to annual $PM_{2.5}$ concentrations in analyses that do not apply population weighting.[72] Analyses show that average maximum annual design values are 40 to 50% higher when compared to annual average $PM_{2.5}$ concentrations estimated without population weighting versus 15% to 18% higher when compared to average annual $PM_{2.5}$ concentrations estimated with population weighting applied (similar to the differences observed for the composite monitor comparison values for the monitor-based epidemiologic studies) (U.S. EPA, 2022b, section 2.3.3.2.4). Given these results, it is worth noting that for the studies using the hybrid modeling approaches, the choice of methodology employed in calculating the study-reported means (*i.e.,* using population weighting or not), and not a difference in estimates of exposure in the study itself, can produce substantially different study-reported mean values, where approaches that do not apply population weighting leading to much lower estimated mean $PM_{2.5}$ concentrations.

Based on these results, and similar to conclusions for the monitor-based studies, the 2022 PA generally concludes that study-reported mean concentrations in the studies that employ hybrid modeling approaches and calculate a population-weighted mean are associated with air quality conditions that would be achieved by meeting annual standard levels that are 15–18% higher than study-reported means. Therefore, an annual standard level that is no more than 15–18% higher than the study-reported means would generally maintain air quality exposures to be below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring. For the studies that utilize hybrid modeling approaches but do not incorporate population weighting in calculating the mean, the annual design values associated with these air quality conditions are expected to be much higher (*i.e.,* 40–50% higher) and this larger difference makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards. Additionally, as noted above in studies that utilize hybrid modeling approaches and that do not incorporate population weighting in calculating the mean (*e.g.,* use each grid cell to calculate a mean $PM_{2.5}$ concentration), the study mean does not reflect the exposure concentrations used in the epidemiologic study to assess the reported association.

The 2022 PA notes that while these analyses can be useful to informing the understanding of the relationship between study-reported mean concentrations and the level of the annual standard, some limitations of this analysis must be recognized (U.S. EPA, 2022a, section 3.3.3.2.1). First, the comparisons used only two hybrid modeling approaches. Although these two hybrid modeling surfaces have been used in a number of recent epidemiologic studies, they represent just two of the many hybrid modeling approaches that have been used in epidemiologic studies to estimate $PM_{2.5}$ concentrations. These methods continue to evolve, with further development and improvement to prediction models that estimate $PM_{2.5}$ concentrations in epidemiologic studies. In addition to differences in hybrid modeling approaches, epidemiologic studies also use different methods to assign a population weighted average $PM_{2.5}$ concentration to their study population, and the assessment presented in the

[71] More details on the evaluation of the two hybrid modeling approaches is provided in section 2.3.3.2.4 of the 2022 PA (U.S. EPA, 2022b).

[72] The annual $PM_{2.5}$ concentrations for the population-weighted averages ranged from 8.2–10.2 $\mu g/m^3$, while those that do not apply population weighting ranged from 7.0–8.6 $\mu g/m^3$. Average maximum annual design values ranged from 9.5 to 11.7 $\mu g/m^3$.

2022 PA does not evaluate all of the potential methods that could be used.

Additionally, while some of these epidemiologic studies also provide information on the broader distributions of exposure estimates and/or health events and the $PM_{2.5}$ concentrations corresponding to the lower percentiles of those data (*e.g.,* 25th and/or 10th), the air quality analysis in the 2022 PA focuses on mean $PM_{2.5}$ concentrations and a similar comparison for lower percentiles of data was not assessed. Therefore, any direct comparison of study-reported $PM_{2.5}$ concentrations corresponding to lower percentiles and annual design values is more uncertain than such comparisons with the mean. Finally, air quality analysis presented in the 2022 PA and detailed above in section I.D.5 included two hybrid modeling-based approaches that used U.S.-based air quality information for estimating $PM_{2.5}$ concentrations. As such, the analyses are most relevant to interpreting the study-reported mean concentrations from U.S. epidemiologic studies and do not provide additional information about how the mean exposures concentrations reported in epidemiologic studies in other countries would compare to annual design values observed in the U.S. In addition, while information from Canadian studies can be useful in assessing the adequacy of the annual standard, differences in the exposure environments and population characteristics between the U.S. and other countries can affect the study-reported mean value and its relationship with the annual standard level. Sources and pollutant mixtures, as well as $PM_{2.5}$ concentration gradients, may be different between countries, and the exposure environments in other countries may differ from those observed in the U.S. Furthermore, differences in population characteristics and population densities can also make it challenging to directly compare studies from countries outside of the U.S. to a design value in the U.S.

As with the experimental studies discussed above, the 2022 PA focuses on epidemiologic studies assessed in the 2019 ISA and ISA Supplement that have the potential to be most informative in reaching decisions on the adequacy of the primary $PM_{2.5}$ standards. The 2022 PA focuses on epidemiologic studies that provide strong support for ''causal'' or ''likely to be causal'' relationships with $PM_{2.5}$ exposures in the 2019 ISA. Further, the 2022 PA also focuses on the health effect associations that are determined in the 2019 ISA and ISA Supplement to be consistent across studies, coherent with the broader body of evidence (*e.g.,* including animal and controlled human exposure studies), and robust to potential confounding by co-occurring pollutants and other factors.[73] In particular the 2022 PA considers the U.S. and Canadian epidemiologic studies to be more useful for reaching conclusions on the current standards than studies conducted in other countries, given that the results of the U.S. and Canadian studies are more directly applicable for quantitative considerations, whereas studies conducted in other countries reflect different populations, exposure characteristics, and air pollution mixtures. Additionally, epidemiologic studies outside of the U.S. and Canada generally reflect higher $PM_{2.5}$ concentrations in ambient air than are currently found in the U.S., and are less relevant to informing questions about adequacy of the current standards.[74] However, and as noted above, the 2022 PA also recognizes that while information from Canadian studies can be useful in assessing the adequacy of the annual standard, there are still important differences between the exposure environments in the U.S. and Canada and interpreting the data (*e.g.,* mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing questions regarding the adequacy of the current or potential alternative the levels of the annual standard. Lastly, the 2022 PA emphasizes multicity/multistate studies that examine health effect associations, as such studies are more encompassing of the diverse atmospheric conditions and population demographics in the U.S. than studies that focus on a single city or State. Figures 3–4 through 3–7 in the 2022 PA summarize the study details for the key U.S. and Canadian epidemiologic studies (U.S. EPA, 2022b, section 3.3.3.2.1).[75]

The key epidemiologic studies identified in the 2022 PA indicate generally positive and statistically significant associations between estimated $PM_{2.5}$ exposures (short- or long-term) and mortality or morbidity across a range of ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.3.3.2.1), report overall mean (or median) $PM_{2.5}$ concentrations, and include those for which the years of $PM_{2.5}$ air quality data used to estimate exposures overlap entirely with the years during which health events are reported.[76] Additionally, for studies that estimate $PM_{2.5}$ exposure using hybrid modeling approaches, the 2022 PA also considers the approach used to estimate $PM_{2.5}$ concentrations and the approach used to validate hybrid model predictions when evaluating those studies as key epidemiologic studies[77] and focuses on those studies that use recent methods based on surfaces that are with fused with monitored $PM_{2.5}$

[73] As described in the Preamble to the ISAs (U.S. EPA, 2015), ''the U.S. EPA emphasizes the importance of examining the pattern of results across various studies and does not focus solely on statistical significance or the magnitude of the direction of the association as criteria of study reliability. Statistical significance is influenced by a variety of factors including, but not limited to, the size of the study, exposure and outcome measurement error, and statistical model specifications. Statistical significance may be informative; however, it is just one of the means of evaluating confidence in the observed relationship and assessing the probability of chance as an explanation. Other indicators of reliability such as the consistency and coherence of a body of studies as well as other confirming data may be used to justify reliance on the results of a body of epidemiologic studies, even if results in individual studies lack statistical significance. Traditionally, statistical significance is used to a larger extent to evaluate the findings of controlled human exposure and animal toxicological studies. Understanding that statistical inferences may result in both false positives and false negatives, consideration is given to both trends in data and reproducibility of results. Thus, in drawing judgments regarding causality, the U.S. EPA emphasizes statistically significant findings from experimental studies, but does not limit its focus or consideration to statistically significant results in epidemiologic studies.''

[74] This emphasis on studies conducted in the U.S. or Canada is consistent with the approach in the 2012 and 2020 reviews of the PM NAAQS (U.S. EPA, 2011, section 2.1.3; U.S. EPA, 2020b, section 3.2.3.2.1) and with approaches taken in other NAAQS reviews. However, the importance of studies in the U.S., Canada, and other countries in informing an ISA's considerations of the weight of the evidence that informs causality determinations is recognized.

[75] The cohorts examined in the studies included in Figure 3–4 to Figure 3–7 of the 2022 PA include large numbers of individuals in the general population, and often also include those populations identified as at-risk (*i.e.,* children, older adults, minority populations, and individuals with pre-existing cardiovascular and respiratory disease).

[76] For some studies of long-term $PM_{2.5}$ exposures, exposure is estimated from air quality data corresponding to only part of the study period, often including only the later years of the health data, and are not likely to reflect the full ranges of ambient $PM_{2.5}$ concentrations that contributed to reported associations. While this approach can be reasonable in the context of an epidemiologic study that is evaluating health effect associations with long-term $PM_{2.5}$ exposures, under the assumption that spatial patterns in $PM_{2.5}$ concentrations are not appreciably different during time periods for which air quality information is not available (*e.g.,* Chen et al., 2016), the 2022 PA focuses on the distribution of ambient $PM_{2.5}$ concentrations that could have contributed to reported health outcomes. Therefore, the 2022 PA identifies studies as key epidemiologic studies when the years of air quality data and health data overlap in their entirety.

[77] Such studies are identified as those that use hybrid modeling approaches for which recent methods and models were used (*e.g.,* recent versions and configurations of the air quality models); studies that are fused with $PM_{2.5}$ data from national monitoring networks (*i.e.,* FRM/FEM data); and studies that reported a thorough model performance evaluation for core years of the study.

concentration data (U.S. EPA, 2022b, section 3.3.3.2.1).

Figure 1 below (U.S. EPA, 2022b, Figure 3–8) highlights the overall mean (or median) $PM_{2.5}$ concentrations reported in key U.S. studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ exposure.[78] For the small subset of studies with available information on the broader distributions of underlying data, Figure 1 below also identifies the study-period $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health events[79] (see Appendix B, Section B.2 of the 2022 PA for more information). Figure 2 (U.S. EPA, 2022a, Figure 3–14) presents overall means of predicted $PM_{2.5}$ concentrations for key U.S. model-based epidemiologic studies that apply aspects of population-weighting, and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events[80] when available (see Appendix B, section B.3 for additional information).[81]

[78] Canadian studies that use ground-based monitors estimate long- or short-term $PM_{2.5}$ exposures are found in Figure 3–9 of the 2022 PA, including concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events, when available (U.S. EPA, 2022b).

[79] That is, 25% of the total health events occurred in study locations with mean $PM_{2.5}$ concentrations (*i.e.,* averaged over the study period) below the 25th percentiles identified in Figure 3–8 of the 2022 PA and 10% of the total health events occurred in study locations with mean $PM_{2.5}$ concentrations below the 10th percentiles identified.

[80] For most studies in Figure 2 below (Figure 3–14 in the 2022 PA), 25th percentiles of exposure estimates are presented. The exception is Di et al. (2017b), for which Figure 2 (U.S. EPA, 2022b, Figure 3–14) presents the short-term $PM_{2.5}$ exposure estimates corresponding to the 25th and 10th percentiles of deaths in the study population (*i.e.,* 25% and 10% of deaths occurred at concentrations below these concentrations). In addition, the authors of Di et al. (2017b) provided population-weighted exposure values. The 10th and 25th percentiles of these population-weighted exposure estimates are 7.9 and 9.5 $\mu g/m^3$, respectively.

[81] Overall mean (or median) $PM_{2.5}$ concentrations reported in key Canadian studies that use model-based approaches to estimate long- or short-term $PM_{2.5}$ concentrations and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events, when available are found in Figure 3–9 of the 2022 PA (U.S. EPA, 2022b).

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Figure 1. Monitor-based $PM_{2.5}$ Concentrations in Key U.S. Epidemiologic Studies. (Asterisks denote studies included in the ISA Supplement)

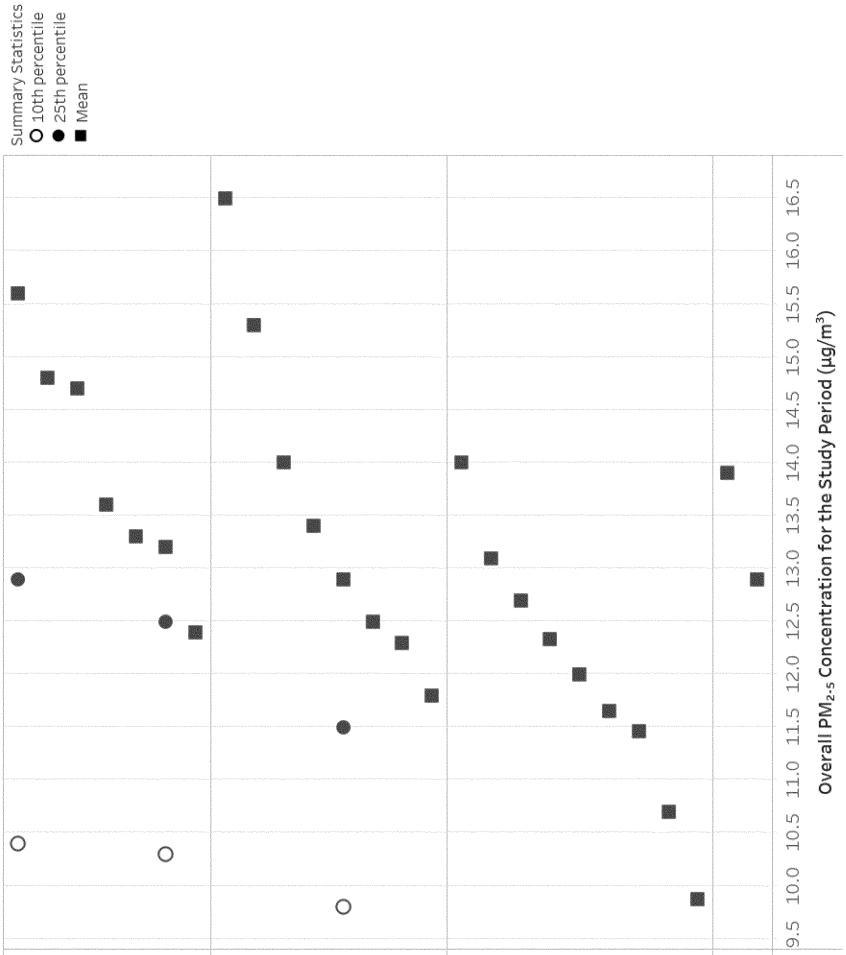
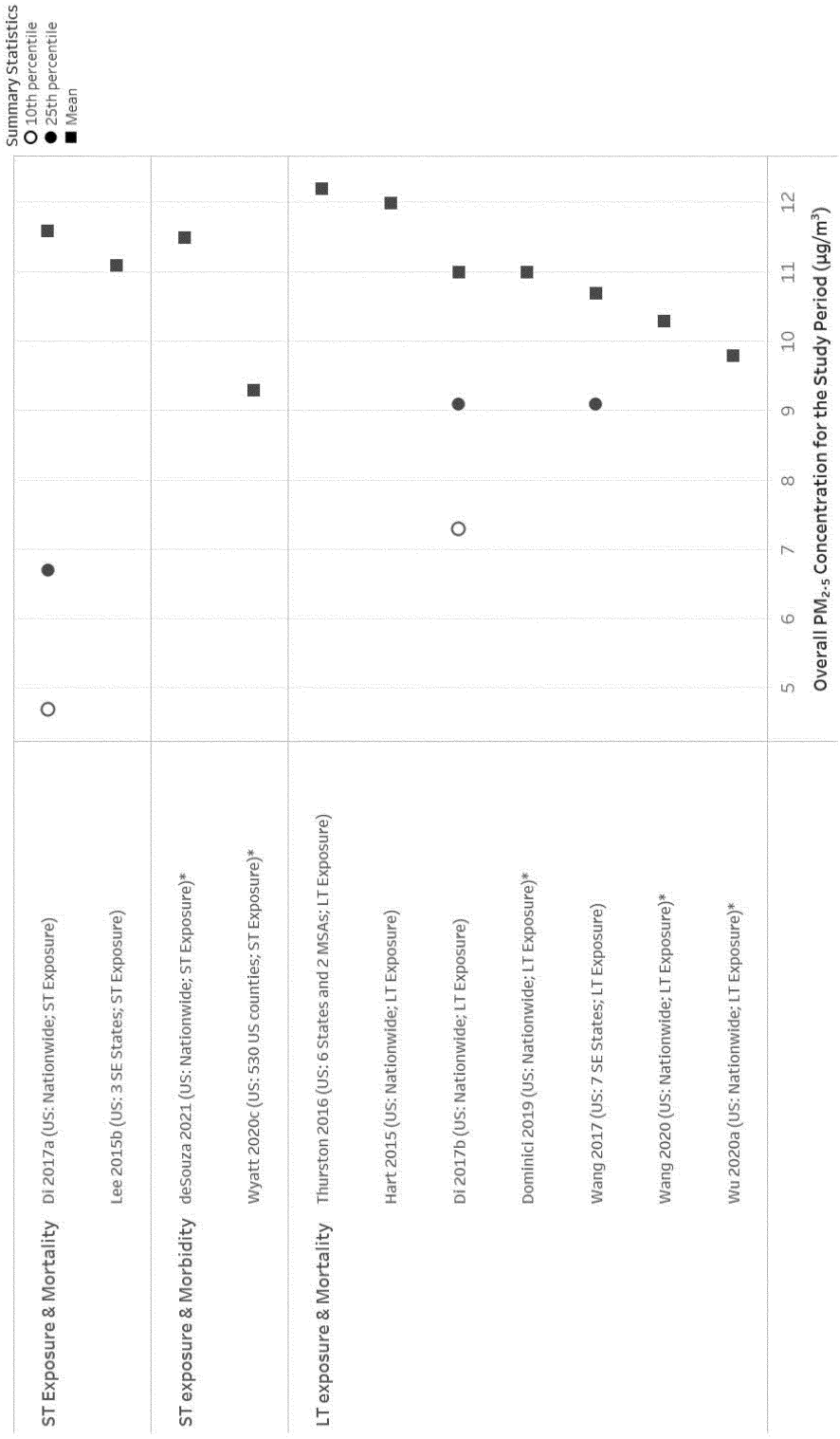


Figure 2. Hybrid Model-Predicted $PM_{2.5}$ Concentrations in Key U.S. Epidemiologic Studies that Apply Aspects of Population-Weighting. (Asterisks denote studies included in the ISA Supplement)



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Based on its evaluation of study-reported mean concentrations, the 2022 PA notes that key epidemiologic studies conducted in the U.S. or Canada report generally positive and statistically significant associations between estimated $PM_{2.5}$ exposures (short- or long-term) and mortality or morbidity across a wide range of ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.3.3.2.1). The 2022 PA makes a number of observations with regard to the study-reported $PM_{2.5}$ concentrations in the key U.S. and Canadian epidemiologic studies.

The 2022 PA first considers the $PM_{2.5}$ concentrations from the key U.S. epidemiologic studies. For studies that use monitors to estimate $PM_{2.5}$ exposures, overall mean $PM_{2.5}$ concentrations range between 9.9 µg/m^3 [82] to 16.5 µg/m^3 (Figure 1 above and

[82] This is generally consistent with, but slightly below, the lowest study-reported mean $PM_{2.5}$ concentration from monitor-based studies available

Continued

U.S. EPA, 2022b, Figure 3–8). For key U.S. epidemiologic studies that use hybrid model-predicted exposures and apply aspects of population-weighting, mean $PM_{2.5}$ concentrations range from 9.3 μg/m³ to just above 12.2 μg/m³ (Figure 2 above and U.S. EPA, 2022b, Figure 3–14). In studies that average up from the grid cell level to the ZIP code, postal code, or census tract level, mean $PM_{2.5}$ concentrations range from 9.8 μg/m³ to 12.2 μg/m³. The one study that population-weighted the grid cell prior to averaging up to the ZIP code or census tract level reported mean $PM_{2.5}$ concentrations of 9.3 μg/m³. Based on air quality analyses noted above, these hybrid modelled epidemiologic studies are expected to report means similar to those from monitor-based studies.

Other key U.S. epidemiologic studies that use hybrid modeling approaches estimate mean $PM_{2.5}$ exposure by averaging each grid cell across the entire study area, whether that be the nation or a region of the country. These studies do not weight the estimated exposure concentrations based on population density or location of health events. As such, the study mean reported in these studies may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. As a result, these reported mean concentrations are the most different (and much lower) than the means reported in monitor-based studies. Due to the methodology employed in calculating the study-reported means and not necessarily a difference in estimates of exposure, these epidemiologic studies are expected to report some of the lowest mean values. For these studies, the reported mean $PM_{2.5}$ concentrations range from 8.1 μg/m³ to 11.9 μg/m³ (U.S. EPA, 2022b, Figure 3–14). As noted above, for studies that utilize hybrid modeling approaches but do not incorporate population weighting into the reported mean calculation, the associated annual design values would be expected to be much higher (*i.e.,* 40–50% higher) than the study-reported means. This larger difference between design values and study-reported mean concentrations makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards (U.S. EPA, 2022b, section 3.3.3.2.1).

In addition to the mean $PM_{2.5}$ concentrations, a subset of the key U.S. epidemiologic studies report $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health data or exposure estimates to provide insight into the concentrations that comprise the lower quartile of the air quality distributions. In studies that use monitors to estimate $PM_{2.5}$ exposures, 25th percentiles of health events correspond to $PM_{2.5}$ concentrations (*i.e.,* averaged over the study period for each study city) at or above 11.5 μg/m³ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 9.8 μg/m³ (*i.e.,* 25% and 10% of health events, respectively, occur in study locations with $PM_{2.5}$ concentrations below these values) (Figure 1 above and U.S. EPA, 2022b, Figure 3–8). Of the key U.S. epidemiologic studies that use hybrid modeling approaches and apply population-weighting to estimate long-term $PM_{2.5}$ exposures, the ambient $PM_{2.5}$ concentrations corresponding to 25th percentiles of estimated exposures are 9.1 μg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14). In key U.S. epidemiologic studies that use hybrid modeling approaches and apply population-weighting to estimate short-term $PM_{2.5}$ exposures, the ambient concentrations corresponding to 25th percentiles of estimated exposures, or health events, are 6.7 μg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14). In key U.S. epidemiologic studies that use hybrid modeling approaches and do not apply population-weighting to estimate $PM_{2.5}$ exposures, the ambient concentrations corresponding to 25th percentiles of estimated exposures, or health events, range from 4.6 to 9.2 μg/m³ (U.S. EPA, 2022b, Figure 3–14).[83] In the key epidemiologic studies that apply hybrid modeling approaches with population-weighting and with information available on the 10th percentile of health events, the ambient $PM_{2.5}$ concentration corresponding to that 10th percentile range from 4.7 μg/m³ to 7.3 μg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14).

The 2022 PA next considers the $PM_{2.5}$ concentrations from the key Canadian epidemiologic studies. Generally, the study-reported mean concentrations in Canadian studies are lower than those reported in the U.S. studies for both monitor-based and hybrid model methods. For the majority of key Canadian epidemiologic studies that use monitor-based exposure, mean $PM_{2.5}$ concentrations generally ranged from 7.0 μg/m³ to 9.0 μg/m³ (U.S. EPA, 2022b, Figure 3–9). For these studies, 25th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 6.5 μg/m³ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 6.4 μg/m³ (U.S. EPA, 2022b, Figure 3–9). For the key Canadian epidemiologic studies that use hybrid model-predicted exposure, the mean $PM_{2.5}$ concentrations are generally lower than in U.S. model-based studies (U.S. EPA, 2022b, Figure 3–10), ranging from approximately 6.0 μg/m³ to just below 10.0 μg/m³ (U.S. EPA, 2022b, Figure 3–11). The majority of the key Canadian epidemiologic studies that used hybrid modeling were completed at the nationwide scale, while four studies were completed at the regional geographic spatial scale. In addition, all the key Canadian epidemiologic studies apply aspects of population weighting, where all grid cells within a postal code are averaged, individuals are assigned exposure at the postal code resolution, and study mean $PM_{2.5}$ concentrations are based on the average of individual exposures. The majority of studies estimating exposure nationwide range between just below 6.0 μg/m³ to 8.0 μg/m³ (U.S. EPA, 2022b, Figure 3–11). One study by Erickson et al. (2020) presents an analysis related immigrant status and length of residence in Canada versus non-immigrant populations, which accounts for the four highest mean $PM_{2.5}$ concentrations which range between 9.0 μg/m³ and 10.0 μg/m³ (U.S. EPA, 2022b, Figure 3–11). The four studies that estimate exposure at the regional scale report mean $PM_{2.5}$ concentrations that range from 7.8 μg/m³ to 9.8 μg/m³ (U.S. EPA, 2022b, Figure 3–11). Three key Canadian epidemiologic studies report information on the 25th percentile of health events. In these studies, the ambient $PM_{2.5}$ concentration corresponding to the 25th percentile is approximately 8.0 μg/m³ in two studies, and 4.3 μg/m³ in a third study (U.S. EPA, 2022b, Figure 3–11).

In addition to the expanded body of evidence from the key U.S. epidemiologic studies discussed above, there are also a subset of epidemiologic studies that have emerged that further inform an understanding of the relationship between $PM_{2.5}$ exposure and health effects, including studies with the highest exposures excluded (restricted analyses), epidemiologic studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.,* used alternative

in the 2020 PA, which was 10.7 μg/m³ (U.S. EPA, 2020a, Figure 3–7).

[83] In the one study that reports 25th percentile exposure estimates of 4.6 μg/m³ (Shi et al., 2016), the authors report that most deaths occurred at or above the 75th percentile of annual exposure estimates (*i.e.,* 10 μg/m³). The short-term exposure estimates accounting for most deaths are not presented in the published study.

methods for confounder control),[84] and accountability studies (U.S. EPA, 2019a, U.S. EPA, 2021a, U.S. EPA, 2022a).

Restricted analyses are studies that examine health effect associations in analyses with the highest exposures excluded, restricting analyses to daily exposures less than the 24-hour primary $PM_{2.5}$ standard and annual exposures less than the annual $PM_{2.5}$ standard. The 2022 PA presents a summary of restricted analyses evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–10). The restricted analyses can be informative in assessing the nature of the association between long-term exposures (*e.g.,* annual average concentrations <12.0 μg/m³) or short-term exposures (*e.g.,* daily concentrations <35 μg/m³) when looking only at exposures to lower concentrations, including whether the association persists in such restricted analyses compared to the same analyses for all exposures, as well as whether the association is stronger, in terms of magnitude and precision, than when completing the same analysis for all exposures. While these studies are useful in supporting the confidence and strength of associations at lower concentrations, these studies also have inherent uncertainties and limitations, including uncertainty in how studies exclude concentrations (*e.g.,* are they excluded at the modeled grid cell level, the ZIP code level) and in how concentrations in studies that restrict air quality data relate to design values for the annual and 24-hour standards. Further, these studies often do not report descriptive statistics (*e.g.,* mean $PM_{2.5}$ concentrations, or concentrations at other percentiles) that allow for additional consideration of this information. As such, while these studies can provide additional supporting evidence for associations at lower concentrations, the 2022 PA notes that there are also limitations in how to interpret these studies when evaluating the adequacy of the current or potential alternative standards.

Restricted analyses provide additional information on the nature of the association between long- or short-term exposures when analyses are restricted to lower $PM_{2.5}$ concentrations and indicate that effect estimates are generally greater in magnitude in the restricted analyses for long- and short-term $PM_{2.5}$ exposure compared to the main analyses. In two U.S. studies that report mean $PM_{2.5}$ concentrations in restricted analyses and that estimate effects associated with long-term exposure to $PM_{2.5}$, the effect estimates are greater in the restricted analyses than in the main analyses. Di et al. (2017a) and Dominici et al. (2019) report positive and statistically significant associations in analyses restricted to concentrations less than 12.0 μg/m³ for all-cause mortality and effect estimates are greater in the restricted analyses than effect estimates reported in main analyses. In addition, both studies report mean $PM_{2.5}$ concentrations of 9.6 μg/m³. While none of the U.S. studies of short-term exposure present mean $PM_{2.5}$ concentrations for the restricted analyses, these studies generally have mean 24-hour average $PM_{2.5}$ concentrations in the main analyses below 12.0 μg/m³, and report increases in the effect estimates in the restricted analyses compared to the main analyses. Additionally, in the one Canadian study of long-term $PM_{2.5}$ exposure, Zhang et al. (2021) conducted analyses where annual $PM_{2.5}$ concentrations were restricted to concentrations below 10.0 μg/m³ and 8.8 μg/m³, which presumably have lower mean concentrations than the mean of 7.8 μg/m³ reported in the main analyses, though restricted analysis mean $PM_{2.5}$ concentrations are not reported. Effect estimates for non-accidental mortality are greater in analyses restricted to $PM_{2.5}$ concentrations less than 10.0 μg/m³, but less in analyses restricted to <8.8 μg/m³.

The second type of studies that have recently emerged and further inform the consideration of the relationship between $PM_{2.5}$ exposure and health effects in the 2022 PA are those that employ alternative methods for confounder control. Alternative methods for confounder control seek to mimic randomized experiments through the use of study design and statistical methods to more extensively account for confounders and are more robust to model misspecification. The 2022 PA presents a summary of the studies that employ alternative methods for confounder control, and employ a variety of statistical methods, which are evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–11). These studies reported consistent results among large study populations across the U.S. and can further inform the relationship between long- and short-term $PM_{2.5}$ exposure and total mortality. Studies that employ alternative methods for confounder control to assess the association between long-term exposure to $PM_{2.5}$ and mortality reduce uncertainties related to confounding and provide additional support for the associations reported in the broader body of cohort studies that examined long-term $PM_{2.5}$ exposure and mortality.

Lastly, there is a subset of epidemiologic studies that assess whether long-term reductions in ambient $PM_{2.5}$ concentrations result in corresponding reductions in health outcomes. These include studies that evaluate the potential for improvements in public health, including reductions in mortality rates, increases in life expectancy, and reductions in respiratory disease as ambient $PM_{2.5}$ concentrations have declined over time. Some of these studies, accountability studies, provide insight on whether the implementation of environmental policies or air quality interventions result in changes/reductions in air pollution concentrations and the corresponding effect on health outcomes.[85] The 2022 PA presents a summary of these studies, which are assessed in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–12). These studies lend support for the conclusion that improvements in air quality are associated with improvements in public health.

More specifically, of the accountability studies that account for changes in $PM_{2.5}$ concentrations due to a policy or the implementation of an intervention and whether there was evidence of changes in associations with mortality or cardiovascular effects as a result of changes in annual $PM_{2.5}$ concentrations, Corrigan et al. (2018), Henneman et al. (2019) and Sanders et al. (2020a) present analyses with starting $PM_{2.5}$ concentrations (or concentrations prior to the policy or intervention) below 12.0 μg/m³. Henneman et al. (2019) explored changes in modeled $PM_{2.5}$ concentrations following the retirement of coal fired power plants in the U.S., and found that reductions from mean annual $PM_{2.5}$ concentrations of 10.0 μg/m³ in 2005 to mean annual $PM_{2.5}$ concentrations of 7.2 μg/m³ in 2012 from coal-fueled power plants resulted in corresponding reductions in the number of cardiovascular-related

[84] As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1–3): ''In the peer-reviewed literature, these epidemiologic studies are often referred to as alternative methods for confounder control. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.,* the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence.''

[85] Given the nature of these studies, the majority tend to focus on time periods in the past during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently (*e.g.,* see U.S. EPA, 2022b, Figure 2–16).

hospital admissions, including for all cardiovascular disease, acute MI, stroke, heart failure, and ischemic heart disease in those aged 65 and older. Corrigan et al. (2018) examined whether there was a change in the cardiovascular mortality rate before (2000–2004) and after (2005–2010) implementation of the first annual $PM_{2.5}$ NAAQS implementation based on mortality data from the National Center for Health Statistics and reported 1.10 (95% confidence interval (CI): 0.37, 1.82) fewer cardiovascular deaths per year per 100,000 people for each 1 μg/m³ reduction in annual $PM_{2.5}$ concentrations. When comparing whether counties met the annual $PM_{2.5}$ standard (attainment counties), there were 1.96 (95% CI: 0.77, 3.15) fewer cardiovascular deaths for each 1 μg/m³ reduction in annual $PM_{2.5}$ concentrations between the two periods for attainment counties, whereas in non-attainment counties (*e.g.,* counties that did not meet the annual $PM_{2.5}$ standard), there were 0.59 (95% CI: − 0.54, 1.71) fewer cardiovascular deaths between the two periods. And lastly, Sanders et al. (2020a) examined whether policy actions (*i.e.,* the first annual $PM_{2.5}$ NAAQS implementation rule in 2005 for the 1997 annual $PM_{2.5}$ standard with a 3-year annual average of 15 μg/m³) reduced $PM_{2.5}$ concentrations and mortality rates in Medicare beneficiaries between 2000–2013. They report evidence of changes in associations with mortality (a decreased mortality rate of ~0.5 per 1,000 in attainment and non-attainment areas) due to changes in annual $PM_{2.5}$ concentrations in both attainment and non-attainment areas. Additionally, attainment areas had starting concentrations below 12.0 μg/m³ prior to implementation of the annual $PM_{2.5}$ NAAQS in 2005. In addition, following implementation of the annual $PM_{2.5}$ NAAQS, annual $PM_{2.5}$ concentrations decreased by 1.59 μg/m³ (95% CI: 1.39, 1.80) which corresponded to a reduction in mortality rates among individuals 65 years and older (0.93% [95% CI: 0.10%, 1.77%]) in non-attainment counties relative to attainment counties. In a life expectancy study, Bennett et al. (2019) reports increases in life expectancy in all but 14 counties (1325 of 1339 counties) that have exhibited reductions in $PM_{2.5}$ concentrations from 1999 to 2015. These studies provide support for improvements in public health following the implementation of policies, including in areas with $PM_{2.5}$ concentrations below the level of the current annual standard, as well as increases in life expectancy in areas with reductions in $PM_{2.5}$ concentrations.

d. Uncertainties in the Health Effects Evidence

The 2022 PA recognizes that there are a number of uncertainties and limitations associated with the available health effects evidence. Although the epidemiologic studies clearly demonstrate associations between long- and short-term $PM_{2.5}$ exposures and health outcomes, several uncertainties and limitations in the health effects evidence remain. Epidemiologic studies evaluating short-term $PM_{2.5}$ exposure and health effects have reported heterogeneity in associations between cities and geographic regions within the U.S. Heterogeneity in the associations observed across epidemiologic studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, and a limited understanding of factors including exposure error related to measurement-related issues, variability in $PM_{2.5}$ composition regionally, and factors that result in differential exposures (*e.g.,* topography, the built environment, housing characteristics, personal activity patterns). Heterogeneity is expected when the methods or the underlying distribution of covariates vary across studies (U.S. EPA, 2019a, p. 6–221). Studies assessed in the 2019 ISA and ISA Supplement have advanced the state of exposure science by presenting innovative methodologies to estimate PM exposure, detailing new and existing measurement and modeling methods, and further informing our understanding of the influence of exposure measurement error due to exposure estimation methods on the associations between $PM_{2.5}$ and health effects reported in epidemiologic studies (U.S. EPA, 2019a, section 1.2.2; U.S. EPA, 2022a). Data from $PM_{2.5}$ monitors continue to be commonly used in health studies as a surrogate for $PM_{2.5}$ exposure, and often provide a reasonable representation of exposures throughout a study area (U.S. EPA, 2019a, section 3.4.2.2; U.S. EPA, 2022a, section 3.2.2.2.2). However, an increasing number of studies employ hybrid modeling methods to estimate $PM_{2.5}$ exposure using data from several sources, often including satellites and models, in addition to ground-based monitors. These hybrid models typically have good cross-validation, especially for $PM_{2.5}$, and have the potential to reduce exposure measurement error and uncertainty in the health effect estimates from epidemiologic models of long-term exposure (U.S. EPA, 2019a, section 3.5; U.S. EPA, 2022a, section 2.3.3).

While studies using hybrid modeling methods have reduced exposure measurement error and uncertainty in the health effect estimates, these studies use a variety of approaches to estimate $PM_{2.5}$ concentrations and to assign exposure to assess the association between health outcomes and $PM_{2.5}$ exposure. This variability in methodology has inherent limitations and uncertainties, as described in more detail in section 2.3.3.1.5 of the 2022 PA, and the performance of the modeling approaches depends on the availability of monitoring data which varies by location. Factors that likely contribute to poorer model performance often coincide with relatively low ambient $PM_{2.5}$ concentrations, in areas where predicted exposures are at a greater distance to monitors, and under conditions where the reliability and availability of key datasets (*e.g.,* air quality modeling) are limited. Thus, uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered.

Regardless of whether a study uses monitoring data or a hybrid modeling approach when estimating $PM_{2.5}$ exposures, one key limitation that persists is associated with the interpretation of the study-reported mean $PM_{2.5}$ concentrations and how they compare to design values, the metric that describes the air quality status of a given area relative to the NAAQS.[86] As discussed above in section II.B.3.b, the overall mean $PM_{2.5}$ concentrations reported by key epidemiologic studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across location (*i.e.,* across multiple monitors or across modeled grid cells) and over time (*i.e.,* over several years). For monitor-based studies, the comparison is somewhat more straightforward than for studies that use hybrid modeling methods, as the monitors used to estimate exposure in the epidemiologic studies are generally the same monitors that are used to calculate design values for a given area. It is expected that areas meeting a $PM_{2.5}$ standard with a particular level would be expected to have average $PM_{2.5}$ concentrations (*i.e.,* averaged across space and over time in the area) somewhat below that standard level., but the difference between the maximum annual design value and

[86] For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of 24-hour $PM_{2.5}$ concentrations, averaged over three years (Appendix N of 40 CFR part 50).

average concentration in an area can be smaller or larger than analyses presented above in section I.D.5.a, likely depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. For studies that use hybrid modeling methods to estimate $PM_{2.5}$ concentrations, the comparison between study-reported mean $PM_{2.5}$ concentrations and design values is more complicated given the variability in the modeling methods, temporal scales (*i.e.,* daily versus annual), and spatial scales (*i.e.,* nationwide versus urban) across studies. Analyses above in section I.D.5.b and detailed more in the 2022 PA (U.S. EPA, 2022b, section 2.3.3.2.4) present a comparison between two hybrid modeling surfaces, which explored the impact of these factors on the resulting mean $PM_{2.5}$ concentrations and provided additional information about the relationship between mean concentrations from studies using hybrid modeling methods and design values. However, the results of those analyses only reflect two surfaces and two types of approaches, so uncertainty remains in understanding the relationship between estimated modeled $PM_{2.5}$ concentrations and design values more broadly across hybrid modeling studies. Moreover, this analysis was completed using two hybrid modeling methods that estimate $PM_{2.5}$ concentrations in the U.S., thus an additional uncertainty includes understanding the relationship between modeled $PM_{2.5}$ concentrations and design values reported in Canada.

In addition, where $PM_{2.5}$ and other pollutants (*e.g.,* ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish whether attenuation of effects in some studies results from copollutant confounding or collinearity with other pollutants in the ambient mixture (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1). Studies evaluated in the 2019 ISA and ISA Supplement further examined the potential confounding effects of both gaseous and particulate copollutants on the relationship between long- and short-term $PM_{2.5}$ exposure and health effects. As noted in the Appendix to the 2019 ISA (U.S. EPA, 2019a, Table A–1), copollutant models are not without their limitations, such as instances for which correlations are high between pollutants resulting in greater copollutant confounding bias in results. However, the studies continue to provide evidence indicating that associations with $PM_{2.5}$ are relatively unchanged in copollutants models (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1).

Another area of uncertainty is associated with other potential confounders, beyond copollutants. Some studies have expanded the examination of potential confounders to not only include copollutants, but also systematic evaluations of the potential impact of inadequate control from long-term temporal trends and weather (U.S. EPA, 2019a, section 11.1.5.1). Analyses examining these covariates further confirm that the relationship between $PM_{2.5}$ exposure and mortality is unlikely to be biased by these factors. Other studies have explored the use of alternative methods for confounder control to more extensively account for confounders and are more robust to model misspecification that can further inform the causality determination for long-term and short-term $PM_{2.5}$ and mortality and cardiovascular effects (U.S. EPA, 2019a, section 11.2.2.4; U.S. EPA, 2022a, sections 3.1.1.3, 3.1.2.3, 3.2.1.2, and 3.2.2.3). These studies indicate that bias from unmeasured confounders can occur in either direction, although controlling for these confounders did not result in the elimination of the association, but instead provided additional support for associations between long-term $PM_{2.5}$ exposure and mortality when accounting for additional confounders (U.S. EPA, 2022a, section 3.2.2.2.6).

Another important limitation associated with the evidence is that, while epidemiologic studies indicate associations between $PM_{2.5}$ and health effects, the currently available evidence does not identify particular $PM_{2.5}$ concentrations that do not elicit health effects. Rather, health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur.

Overall, evidence assessed in the 2019 ISA and ISA Supplement continues to indicate a linear, no-threshold C–R relationship for $PM_{2.5}$ concentrations >8 $\mu g/m^3$. However, uncertainties remain about the shape of the C–R curve at $PM_{2.5}$ concentrations <8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2).

There are also a number of uncertainties and limitations associated with the experimental evidence (*i.e.,* controlled human exposure studies and animal toxicological studies). With respect to controlled human exposure studies, the PA recognizes that these studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects. These studies, therefore, often do not include populations that are at increased risk of $PM_{2.5}$-related health effects, including children, older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations. With respect to animal toxicological studies, while these studies often examine more severe health outcomes and longer exposure durations and higher exposure concentrations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects, to human populations.

Consideration of health effects are informed by the epidemiologic, controlled human exposure, and animal toxicological studies. The evaluation and integration of the scientific evidence in the ISA focuses on evaluating the findings from the body of evidence across disciplines, including evaluating the strengths and weaknesses in the overall collection of studies across disciplines. Integrating evidence across disciplines can strengthen causal inference, such that a weak inference from one line of evidence can be addressed by other lines of evidence, and coherence of these lines of evidence can add support to a cause-effect interpretation of the association. Evaluation and integration of the evidence also includes consideration of uncertainties that are inherent in the scientific findings (U.S. EPA, 2015, pp. 13–15), some of which are described above.

3. Summary of Exposure and Risk Estimates

Beyond the consideration of the scientific evidence, discussed above in section II.B, the EPA also considers the extent to which new or updated quantitative analyses of $PM_{2.5}$ air quality, exposure, or health risks could inform conclusions on the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards. Additionally, the 2022 PA includes an at-risk analysis that assesses $PM_{2.5}$-attributable risk associated with $PM_{2.5}$ air quality that has been adjusted to simulate air quality scenarios of policy

interest (*e.g.,* ''just meeting'' the current or potential alternative standards). Drawing on the summary in section II.C of the proposal, the sections below provide a brief overview of key aspects of the assessment design (II.A.3.a), key limitations and uncertainties (II.A.3.b), and exposure/risk estimates (II.A.3.c).

a. Key Design Aspects

Risk assessments combine data from multiple sources and involve various assumptions and uncertainties. Input data for these analyses includes C–R functions from epidemiologic studies for each health outcome and ambient annual or 24-hour $PM_{2.5}$ concentrations for the study areas utilized in the risk assessment (U.S. EPA, 2022b, section 3.4.1). Additionally, quantitative and qualitative methods were used to characterize variability and uncertainty in the risk estimates (U.S. EPA, 2022b, section 3.4.1.7).

Concentration-response functions used in the risk assessment are from large, multicity U.S. epidemiologic studies that evaluate the relationship between $PM_{2.5}$ exposures and mortality. Epidemiologic studies and concentration-response studies that were used in the risk assessment to estimate risk were identified using criteria that take into account factors such as study design, geographic coverage, demographic populations, and health endpoints (U.S. EPA, 2022b, section 3.4.1.1).[87] The risk assessment focuses on all-cause or nonaccidental mortality associated with long-term and short-term $PM_{2.5}$ exposures, for which the 2019 ISA concluded that the evidence provides support for a ''causal relationship'' (U.S. EPA, 2022b, section 3.4.1.2).[88]

As described in more detail in the 2022 PA, the risk assessment first estimated health risks associated with air quality for 2015 adjusted to simulate ''just meeting'' the current primary $PM_{2.5}$ standards (*i.e.,* the annual standard with its level of 12.0 μg/m^3 and the 24-hour standard with its level of 35 μg/m^3). Air quality modeling was then used to simulate air quality just meeting an alternative standard with a level of 10.0 μg/m^3 (annual) and 30 μg/m^3 (24-hour). In addition to the model-based approach, for the subset of 30 areas controlled by the annual standard linear interpolation and extrapolation were employed to simulate just meeting alternative annual standards with levels of 11.0 (interpolated between 12.0 and 10.0 μg/m^3), 9.0 μg/m^3, and 8.0 μg/m^3 (both extrapolated from 12.0 and 10.0 μg/m^3) (U.S. EPA, 2022b, section 3.4.1.3). The 2022 PA notes that there is greater uncertainty regarding whether a revised 24-hour standard (*i.e.,* with a lower level) is needed to further limit ''peak'' $PM_{2.5}$ concentration exposure and whether a lower 24-hour standard level would most effectively reduce $PM_{2.5}$-associated health risks associated with ''typical'' daily exposures. The risk assessment estimates health risks associated with air quality adjusted to meet a revised 24-hour standard with a level of 30 μg/m^3, in conjunction with estimating the health risks associated with meeting a revised annual standard with a level of 10.0 μg/m^3 (U.S. EPA, 2022b, section 3.4.1.3). More details on the air quality adjustment approaches used in the risk assessment are described in section 3.4.1.4 and Appendix C of the 2022 PA (U.S. EPA, 2022b).

When selecting U.S. study areas for inclusion in the risk assessment, the available ambient monitors, geographic diversity, and ambient $PM_{2.5}$ air quality concentrations were taken into consideration (U.S. EPA, 2022b, section 3.4.1.4). When these factors were applied, 47 urban study areas were identified, which include nearly 60 million people aged 30–99, or approximately 30% of the U.S population in this age range (U.S. EPA, 2022b, section 3.4.1.5, Appendix C, section C.1.3). Of the 47 study areas, there were 30 study areas where just meeting the current standards is controlled by the annual standard,[89] 11 study areas where just meeting the current standards is controlled by the daily standard,[90] and 6 study areas where the controlling standard differed depending on the air quality adjustment approach (U.S. EPA, 2022b, section 3.4.1.5).[91]

In addition to the overall risk assessment, the 2022 PA also includes an at-risk analysis and estimates exposures and health risks of specific populations identified as at-risk that would be allowed under the current and potential alternative standards to further inform the Administrator's conclusions regarding the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards. In so doing, the 2022 PA evaluates exposure and $PM_{2.5}$ mortality risk for older adults (*e.g.,* 65 years and older), stratified for White, Black, Asian, Native American, Non-Hispanic, and Hispanic individuals residing in the same study areas included in the overall risk assessment. This analysis utilizes a recent epidemiologic study that provides race- and ethnicity-specific risk coefficients (Di et al., 2017b).

b. Key Limitations and Uncertainties

Uncertainty in risk estimates (*e.g.,* in the size of risk estimates) can result from a number of factors, including the assumptions about the shape of the C–R function with mortality at low ambient PM concentrations, the potential for confounding and/or exposure measurement error in the underlying epidemiologic studies, and the methods used to adjust $PM_{2.5}$ air quality. More specifically, the use of air quality modeling to adjust $PM_{2.5}$ concentrations are limited as they rely on model predictions, are based on emission changes scaled by fixed percentages, and use only two of the full set of possible emission scenarios and linear interpolation/extrapolation to adjust air quality that may not fully capture potential non-linearities associated with real-world changes in air quality. Additionally, the selection of case study areas is limited to urban areas predominantly located CA and in the Eastern U.S. that are controlled by the annual standard. While the risk assessment does not report quantitative uncertainty in the risk estimates as exposure concentrations are reduced, it does provide information on the distribution of concentrations associated with the risk estimates when evaluating progressively lower alternative annual standards. Based on these data, as lower alternative annual standards are evaluated, larger proportions of the distributions in risk occur at or below 10 μg/m^3 (at concentrations below or near most of the study-reported means from the key U.S. epidemiologic studies) and at or below 8 μg/m^3 (the concentration at which the ISA reports increasing uncertainty in the shape of the C–R curve based on the body of epidemiologic evidence).

[87] Additional detail regarding the selection of epidemiologic studies and specification of C–R functions is provided in the 2022 PA (U.S. EPA, 2022b, Appendix C, section C.1.1).

[88] While the 2019 ISA also found that evidence supports the determination of a ''causal relationship'' between long- and short-term $PM_{2.5}$ exposures and cardiovascular effects, cardiovascular mortality was not included as a health outcome as it will be captured in the estimates of all-cause mortality.

[89] For these areas, the annual standard is the ''controlling standard'' because when air quality is adjusted to simulate just meeting the current or potential alternative annual standards, that air quality also would meet the 24-hour standard being evaluated.

[90] For these areas, the 24-hour standard is the controlling standard because when air quality is adjusted to simulate just meeting the current or potential alternative 24-hour standards, that air quality also would meet the annual standard being evaluated. Some areas classified as being controlled by the 24-hour standard also violate the annual standard.

[91] In these 6 areas, the controlling standard depended on the air quality adjustment method used and/or the standard scenarios evaluated.

Similarly, the at-risk analysis is also subject to many of these same uncertainties noted above. Additionally, the at-risk analysis included C–R functions from only one study (Di et al., 2017b), which reported associations between long-term $PM_{2.5}$ exposures and mortality, stratified by race/ethnicity, in populations age 65 and older, as opposed to the multiple studies used in the overall risk assessment to convey risk estimate variability. These and other sources of uncertainty in the overall risk assessment and the at-risk analyses are characterized in more depth in the 2022 PA (U.S. EPA, 2022b, section 3.4.1.7, section 3.4.1.8, Appendix C, section C.3).

c. Summary of Risk Estimates

Although limitations in the underlying data and approaches lead to some uncertainty regarding estimates of $PM_{2.5}$-associated risk, the risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. For example, when air quality in the 47 study areas is adjusted to simulate just meeting the current standards, the risk assessment estimates up to 45,100 deaths in 2015 are attributable to long-term $PM_{2.5}$ exposures associated with just meeting the current annual and 24-hour $PM_{2.5}$ standards (U.S. EPA, 2022b, section 3.4.2.1). Additionally, as described in more detail in the 2022 PA, the at-risk analysis suggests that a lower annual standard level (*i.e.,* below 12 $\mu g/m^3$ and down as low as 8 $\mu g/m^3$) will help to reduce $PM_{2.5}$ exposure and may also help to mitigate exposure and risk disparities in populations identified as particularly at-risk for adverse effects from PM exposures (*i.e.,* minority populations).

Compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce $PM_{2.5}$-associated health risks in the 30 study areas controlled by the annual standard by about 7–9% for a level of 11.0 $\mu g/m^3$, 15–19% for a level of 10.0 $\mu g/m^3$, 22–28% for a level of 9.0 $\mu g/m^3$, and 30–37% for a level of 8.0 $\mu g/m^3$) (U.S. EPA, 2022b, Table 3–17). Meeting a revised annual standard with a lower level may also help to mitigate exposure and risk disparities in populations identified as particularly at-risk for adverse effects from PM exposures (*i.e.,* minority populations) in simulated scenarios just meeting alternative annual standards. However, though reduced, disparities by race and ethnicity persist even at an alternative annual standard level of 8 $\mu g/m^3$, the lowest alternative annual standard included in the risk assessment (U.S. EPA, 2022b, section 3.4.2.4).

Revising the level of the 24-hour standard to 30 $\mu g/m^3$ is estimated to lower $PM_{2.5}$-associated risks across a more limited population and number of areas than revising the annual standard (U.S. EPA, 2022, section 3.4.2.4). Risk reduction predictions are largely confined to areas located in the western U.S., several of which are also likely to experience risk reductions upon meeting a revised annual standard. In the 11 areas controlled by the 24-hour standard, when air quality is simulated to just meet the current 24-hour standard, $PM_{2.5}$ exposures are estimated to be associated with as many as 2,570 deaths annual. Compared to just meeting the current standard, air quality just meeting an alternative 24-hour standard level of 30 $\mu g/m^3$ is associated with reductions in estimated risk of 9–13% (U.S. EPA, 2022b, section 3.4.2.3).

B. Conclusions on the Primary $PM_{2.5}$ Standards

In drawing conclusions on the adequacy of the current primary $PM_{2.5}$ standards, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the 2012 and 2020 reviews and reflects upon the body of evidence and information newly available in this reconsideration. In so doing, the Administrator has taken into account both evidence-based and risk-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of health effects related to $PM_{2.5}$ exposure presented in the 2019 ISA and ISA Supplement (summarized in the proposal in sections II.B (88 FR 5580, January 27, 2023) and II.D.2.a (88 FR 5609, January 27, 2023), and also in section II.A.2 above) to address key policy-relevant questions in the reconsideration. Similarly, the risk-based considerations draw upon the assessment of population exposure and risk (summarized in the proposal in sections II.C (88 FR 5605, January 27, 2023) and II.D.2.b (88 FR 5614, January 27, 2023), and also in section II.A.3 above) in addressing policy-relevant questions focused on the potential for $PM_{2.5}$ exposures associated with mortality under air quality conditions just meeting the current and potential alternative standards.

The approach to reviewing the primary standards is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (*i.e.,* neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish a primary standard at a zero-risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of sensitive groups, with an adequate margin of safety.

The decisions on the adequacy of the current primary $PM_{2.5}$ standards described below is a public health policy judgment by the Administrator that draws on the scientific evidence for health effects, quantitative analyses of population exposures and/or health risks, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. The four basic elements of the NAAQS (*i.e.,* indicator, averaging time, form, and level) have been considered collectively in evaluating the public health protection afforded by the current standards.

Section II.B.2 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section II.D.3 of the proposal (88 FR 5617, January 27, 2023). The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections II.B.1 and II.B.3, respectively. The Administrator's final conclusions in this reconsideration regarding the adequacy of the current primary $PM_{2.5}$ standards and whether any revisions are appropriate are described in section II.B.4.

1. CASAC Advice

As part of its review of the 2019 draft PA, the CASAC provided advice on the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ standards. Its advice is documented in

a letter sent to the EPA Administrator (Cox, 2019b). In this letter, the committee recommended retaining the current 24-hour $PM_{2.5}$ standard but did not reach consensus on whether the scientific and technical information support retaining or revising the current annual standard. In particular, though the CASAC agreed that there is a long-standing body of health evidence supporting relationships between $PM_{2.5}$ exposures and various health outcomes, including mortality and serious morbidity effects, individual CASAC members ''differ[ed] in their assessments of the causal and policy significance of these associations'' (Cox, 2019b, p. 8 of consensus responses). Drawing from this evidence, ''some CASAC members'' expressed support for retaining the current annual standard while ''other members'' expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p.1 of letter). These views are summarized below.

The CASAC members who supported retaining the current annual standard expressed the view that substantial uncertainty remains in the evidence for associations between $PM_{2.5}$ exposures and mortality or serious morbidity effects. These committee members asserted that ''such associations can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019b, p. 8 of consensus responses). They noted that associations do not necessarily reflect causal effects, and they contended that recent epidemiologic studies assessed in the 2019 ISA that report positive associations at lower estimated exposure concentrations mainly confirm what was anticipated or already assumed in setting the 2012 NAAQS. In particular, they concluded that such studies have some of the same limitations as prior studies and do not provide new information calling into question the existing standard. They further asserted that ''accountability studies provide potentially crucial information about whether and how much decreasing $PM_{2.5}$ causes decreases in future health effects'' (Cox, 2019b, p. 10 of consensus responses), and they cited recent reviews (*i.e.,* Henneman et al., 2017; Burns et al., 2019) to support their position that in such studies, ''reductions of $PM_{2.5}$ concentrations have not clearly reduced mortality risks'' (Cox, 2019b, p. 8 of consensus responses). Thus, the committee members who supported retaining the current annual standard advise that, ''while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations'' (Cox, 2019b, p. 8 of consensus responses).

These members of the CASAC further concluded that the quantitative risk assessment included in the 2019 draft PA does not provide a valid basis for revising the current standards. This conclusion was based on concerns that (1) ''the risk assessment treats regression coefficients as causal coefficients with no justification or validation provided for this decision;'' (2) the estimated regression concentration-response functions ''have not been adequately adjusted to correct for confounding, errors in exposure estimates and other covariates, model uncertainty, and heterogeneity in individual biological (causal) [concentration-response] functions;'' (3) the estimated concentration-response functions ''do not contain quantitative uncertainty bands that reflect model uncertainty or effects of exposure and covariate estimation errors;'' and (4) ''no regression diagnostics are provided justifying the use of proportional hazards . . . and other modeling assumptions'' (Cox, 2019b, p. 9 of consensus responses). These committee members also contended that details regarding the derivation of concentration-response functions, including specification of the beta values and functional forms, were not well-documented, hampering the ability of readers to evaluate these design details. Thus, these members ''think that the risk characterization does not provide useful information about whether the current standard is protective'' (Cox, 2019b, p. 11 of consensus responses).

Drawing from their evaluation of the evidence and the risk assessment in the 2019 draft PA, these committee members concluded that ''the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the . . . 2012 $PM_{2.5}$ annual standard'' (Cox, 2019b, p.1 of letter).

In contrast, ''[o]ther members of CASAC conclude[d] that the weight of the evidence, particularly reflecting recent epidemiology studies showing positive associations between $PM_{2.5}$ and health effects at estimated annual average $PM_{2.5}$ concentrations below the current standard, does reasonably call into question the adequacy of the 2012 annual $PM_{2.5}$ [standard] to protect public health with an adequate margin of safety'' (Cox, 2019b, p.1 of letter). The committee members who supported this conclusion noted that the body of health evidence for $PM_{2.5}$ not only includes the repeated demonstration of associations in epidemiologic studies, but also includes support for biological plausibility established by controlled human exposure and animal toxicology studies. They pointed to recent studies demonstrating that the associations between $PM_{2.5}$ and health effects occur in a diversity of locations, in different time periods, with different populations, and using different exposure estimation and statistical methods. They concluded that ''the entire body of evidence for PM health effects justifies the causality determinations made in the Draft PM ISA'' (Cox, 2019b, p. 8 of consensus responses).

The members of the CASAC who supported revising the current annual standard particularly emphasized recent findings of associations with $PM_{2.5}$ in areas with average long-term $PM_{2.5}$ concentrations below the level of the annual standard and studies that show positive associations even when estimated exposures above 12 $\mu g/m^3$ are excluded from analyses. They found it ''highly unlikely'' that the extensive body of evidence indicating positive associations at low estimated exposures could be fully explained by confounding or by other non-causal explanations (Cox, 2019b, p. 8 of consensus responses). They additionally concluded that ''the risk characterization does provide a useful attempt to understand the potential impacts of alternate standards on public health risks'' (Cox, 2019b, p. 11 of consensus responses). These CASAC members concluded that the available evidence reasonably calls into question the protection provided by the current primary $PM_{2.5}$ standards and supports revising the annual standard to increase that protection (Cox, 2019b).

As a part of this reconsideration, the CASAC reviewed the 2021 draft PA (developed to support the reconsideration as described in section I.C.5 above). As a part of their review of the 2021 draft PA, the CASAC provided advice on the adequacy of the current primary $PM_{2.5}$ standards. The range of views summarized here generally reflects differing judgments as to the relative weight to place on various types of evidence, the risk-based information, and the associated uncertainties, as well as differing judgments about the importance of various $PM_{2.5}$-related health effects from a public health perspective.

In its comments on the 2021 draft PA, the CASAC stated that: ''[o]verall the CASAC finds the Draft PA to be well-

written and appropriate for helping to 'bridge the gap' between the agency's scientific assessments and quantitative technical analyses, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS)'' (Sheppard, 2022a, p. 1 of consensus letter). The CASAC also stated that the ''[d]raft PA adequately captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the 2019 ISA and Draft ISA Supplement of $PM_{2.5}$-related health effects'' (Sheppard, 2022b, p. 2 of consensus letter). The CASAC also stated that ''[t]he interpretation of the risk assessment for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ annual standard is appropriate given the scientific findings presented'' (Sheppard, 2022a, p. 2 of consensus letter).

With regard to the adequacy of the current primary annual $PM_{2.5}$ standard, ''all CASAC members agree that the current level of the annual standard is not sufficiently protective of public health and should be lowered'' (Sheppard, 2022a, p. 2 of consensus letter). Additionally, ''the CASAC reached consensus that the indicator, form, and averaging time should be retained, without revision'' (Sheppard, 2022a, p. 2 of consensus letter). With regard to the level of the primary annual $PM_{2.5}$ standard, the CASAC had differing recommendations for the appropriate range for an alternative level. The majority of the CASAC ''judge[d] that an annual average in the range of 8–10 $\mu g/m^3$'' was most appropriate, while the minority of the CASAC members stated that ''the range of the alternative standard of 10–11 $\mu g/m^3$ is more appropriate'' (Sheppard, 2022a, p. 16 of consensus responses). The CASAC did highlight, however, that ''the alternative standard level of 10 $\mu g/m^3$ is within the range of acceptable alternative standards recommended by all CASAC members, and that an annual standard below 12 $\mu g/m^3$ is supported by a larger and coherent body of evidence'' (Sheppard, 2022a, p. 16 of consensus responses).

In reaching conclusions on a recommended range of 8–10 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard, the majority of the CASAC placed weight on various aspects of the available scientific evidence and quantitative risk assessment information discussed in the 2021 draft PA (Sheppard, 2022a, p. 16 of consensus responses). In particular, these members cited recent U.S.- and Canadian-based epidemiologic studies that show positive associations between $PM_{2.5}$ exposure and mortality with study-reported mean concentrations below 10 $\mu g/m^3$. Further, these members also noted that the lower portions of the air quality distribution (*i.e.,* concentrations below the mean) provide additional information to support associations between health effects and $PM_{2.5}$ concentrations lower than the reported long-term mean concentration. In addition, the CASAC members recognized that the available evidence has not identified a threshold concentration, below which an association no longer remains, pointing to the conclusion in the draft ISA Supplement that the ''evidence remains clear and consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations >8 $\mu g/m^3$'' (Sheppard, 2022a, p. 16 of consensus responses). Finally, these CASAC members placed weight on the at-risk analysis as providing support for protection of at-risk demographic groups, including minority populations.

In recommending a range of 10–11 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard, the minority of the CASAC emphasized that there were few key epidemiologic studies that reported positive and statistically significant health effects associations for $PM_{2.5}$ air quality distributions with overall mean concentrations below 9.6 $\mu g/m^3$ (Sheppard, 2022a, p. 17 of consensus responses). In so doing, the minority of the CASAC specifically noted the variability in the relationship between study-reported means and area annual design values based on the methods utilized in the studies, noting that design values are generally higher than area average exposure levels. Further, the minority of the CASAC stated that ''uncertainties related to copollutants and confounders make it difficult to justify a recommendation below 10–11 $\mu g/m^3$'' (Sheppard, 2022a, p. 17 of consensus responses). Finally, the minority of the CASAC placed less weight on the risk assessment results, noting large uncertainties, including the approaches used for adjusting air quality to simulate just meeting the current and alternative standards.

With regard to the current primary 24-hour $PM_{2.5}$ standard, in their review of the 2021 draft PA, the CASAC did not reach consensus regarding the adequacy of the public health protection provided by the current standard. As described further below, the majority of the CASAC members concluded ''that the available evidence calls into question the adequacy of the current 24-hour standard'' (Sheppard, 2022a, p. 3 of consensus letter), while the minority of the CASAC members agreed with ''the EPA's preliminary conclusion [in the draft PA] to retain the current 24-hour $PM_{2.5}$ standard without revision'' (Sheppard, 2022a, p. 4 of consensus letter). The CASAC recommended that in future reviews, the EPA should also consider alternative forms for the primary 24-hour $PM_{2.5}$ standard. Specifically, the CASAC ''suggests considering a rolling 24-hour average and examining alternatives to the 98th percentile of the 3-year average,'' pointing to concerns that computing 24-hour average $PM_{2.5}$ concentrations using the current midnight-to-midnight timeframe could potentially underestimate the effects of high 24-hour exposures, especially in areas with wood-burning stoves and wintertime stagnation (Sheppard, 2022a, p. 18 of consensus responses).

As noted above, the majority of the CASAC favored revising the level of the primary 24-hour $PM_{2.5}$ standard, suggesting that a range of 25–30 $\mu g/m^3$ would be adequately protective. In so doing, the majority of the CASAC placed weight on the available epidemiologic evidence, including epidemiologic studies that restricted analyses to 24-hour $PM_{2.5}$ concentrations below 25 $\mu g/m^3$. These members also placed weight on results of controlled human exposure studies with exposures close to the current standard, which they note provide support for the epidemiologic evidence to lower the standard. These members noted the limitations in using controlled human exposure studies alone in considering the adequacy of the 24-hour standard, recognizing that controlled human exposure studies preferentially recruit less susceptible individuals and have a typical exposure duration shorter than 24 hours. These members also placed ''greater weight on the scientific evidence than on the values estimated by the risk assessment,'' citing their concerns that the risk assessment ''may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective'' (Sheppard, 2022a, p. 17 of consensus responses). Furthermore, these CASAC members ''also are less confident that the annual standard could adequately protect against health effects of short-term exposures'' (Sheppard, 2022a, p. 17 of consensus responses).

The minority of the CASAC agreed with the EPA's preliminary conclusion in the 2021 draft PA to retain the current primary 24-hour $PM_{2.5}$ standard. In so doing, the minority of the CASAC placed greater weight on the risk assessment, noting that the risk

assessment accounts for both the level and the form of the current standard and the manner by which attainment with the standard is determined. Further, the minority of the CASAC stated that the ''risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks'' and therefore, ''the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations'' (Sheppard, 2022a, p. 18 of consensus responses). Further, the minority of the CASAC placed more weight on the controlled human exposure studies, which show ''effects at $PM_{2.5}$ concentrations well above those typically measured in areas meeting the current standards'' and which suggest that ''the current standards are providing adequate protection against these exposures'' (Sheppard, 2022a, p. 18 of consensus responses).

While the CASAC members expressed differing opinions on the appropriate revisions to the current standards, they did ''find that both primary standards, 24-hour and annual, are critical to protect public health given the evidence on detrimental health outcomes at both short-term and long-term exposures including peak events'' (Sheppard, 2022a, p. 13 of consensus responses). The comments from the CASAC also took note of uncertainties that remain in this reconsideration of the primary $PM_{2.5}$ standards and they identified a number of additional areas for future research and data gathering and dissemination that would inform future reviews of the primary $PM_{2.5}$ NAAQS (Sheppard, 2022a, pp. 14–15 of consensus responses).

2. Basis for the Proposed Decision

In reaching his proposed decisions to revise the level of the primary annual $PM_{2.5}$ standard from its current level of 12.0 $\mu g/m^3$ to within the range of 9.0 to 10.0 $\mu g/m^3$, and to retain the current primary 24-hour $PM_{2.5}$ standard (88 FR 5558, January 27, 2023), the Administrator carefully considered the assessment of the current evidence and conclusions reached in the 2019 ISA and ISA Supplement; the currently available exposure and risk information, including associated limitations and uncertainties, described in detail in the 2022 PA; the considerations and staff conclusions and associated rationales presented in the 2022 PA; the advice and recommendations from the CASAC; and public comments that had been offered up to that point (88 FR 5558, January 27, 2023).

In reaching his proposed conclusions on whether the currently available scientific evidence and quantitative risk-based information support or call into question the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ standards, and as is the case with NAAQS reviews in general, the extent to which the current primary $PM_{2.5}$ standards are judged to be adequate will depend on a variety of factors, including science policy and public health policy judgments to be made by the Administrator on the strength and uncertainties of the scientific evidence. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the weight to place on, different aspects of the results of the risk assessment for the study areas included and the associated uncertainties. Thus, in reaching proposed conclusions of the current standards, the Administrator recognized that such a determination depends in part on judgments regarding aspects of the evidence and risk estimates, and judgments about the degree of protection that is requisite to protect public health with an adequate margin of safety.

The Administrator's full rationale for his proposed conclusions is presented in section II.D.3 of proposal (88 FR 5658, January 27, 2023), but is also briefly summarized here. In reaching the proposed decision to revise the annual standard level to 9–10 $\mu g/m^3$, the Administrator placed weight on the full body of scientific information. He noted that the 2019 ISA finds that exposure to $PM_{2.5}$ causes mortality and cardiovascular effects and is likely to cause respiratory effects, cancer, and nervous system effects as detailed further in section II.B.1 of the proposal. As detailed further in section II.B.4 of the proposal, he additionally noted that the 2019 ISA identifies at-risk populations at greater risk of health effects from exposure to $PM_{2.5}$, including children, older adults, people with pre-existing respiratory or cardiovascular disease, minority populations, and low socioeconomic status (SES) populations.

The Administrator also recognized that epidemiologic studies provide the strongest scientific evidence when evaluating the adequacy of the level of the annual standard. He noted that there is no specific point in the air quality distribution of any epidemiologic study that represents a 'bright line' at and above which effects have been observed and below which effects have not been observed. In his proposed decision, he noted previous decision-making frameworks, which placed weight on values at or near the study-reported mean $PM_{2.5}$ concentrations, which is where the most confidence in the reported association of the epidemiologic study exists. He further noted that there are a number of epidemiologic studies available in this reconsideration that use new $PM_{2.5}$ exposure estimation techniques (*e.g.,* hybrid modeling) that were not used in epidemiologic studies that were available in previous reviews. These recent epidemiologic studies that use new exposure estimation techniques report long-term mean $PM_{2.5}$ concentrations that are well below corresponding design values, which is an important consideration in reaching decisions on the level of the annual $PM_{2.5}$ standard.

In reaching his proposed decision, the Administrator noted that a level of 9–10 $\mu g/m^3$ would near or below the reported 25th percentiles in key U.S. based epidemiologic studies, while also recognizing that he has less confidence in the magnitude and significance of the association at even lower percentiles (*e.g.,* 10th percentile), where even fewer health events are observed. The Administrator also noted that a proposed level of 9–10 $\mu g/m^3$ would be near the mean $PM_{2.5}$ reported in Canadian based studies, though he also recognized that there are a number of factors associated with the studies in Canada (*e.g.,* exposure environments) that make it more difficult to compare mean concnetrations from Canadian studies to design values, which determine compliance with the standard in the U.S.

The Administrator took note of additional pieces of scientific evidence, which were not available in previous reviews, including restricted analyses, which support that the association seen in epidemiologic studies does not just occur from the peaks of the exposure distribution. Additionally, he notes that a level of 9–10 $\mu g/m^3$ would be below the starting concentration in newly available accountability studies, though he did note that it is more difficult to interpret these studies in the context of selecting the level of the annual $PM_{2.5}$ standard.

Further, the Administrator took into consideration the advice of the CASAC, noting that all members included 10 $\mu g/m^3$ in their recommended range, and that the proposed range of 9–10 $\mu g/m^3$ for the level of the primary annual $PM_{2.5}$ standard was within the range recommended by the majority of the CASAC.

In reaching the proposed conclusion of a range between 9–10 $\mu g/m^3$, the Administrator noted that a level as high

as 11 μg/m³ might not provide an adequate margin of safety, given that 11 μg/m³ was well above many of the epidemiologic study-reported mean $PM_{2.5}$ concentrations. Additionally, the Administrator noted the uncertainties associated with the scientific and quantitative information supporting a level as low as 8 μg/m³, which call into question the potential public health improvements of a standard below 9 μg/m³. The Administrator specifically noted the lack of key U.S. studies with mean concentrations below 9.3 μg/m³ and he further noted that the risk assessment suggests that the risk remaining under a standard of 8 μg/m³ would occur at very low concentrations (*e.g.,* mainly 7 μg/m³ and below).

As such, the Administrator's proposed decision noted that the current $PM_{2.5}$ annual standard did not adequately provide requisite protection against exposures to $PM_{2.5}$ and that a proposed range of 9–10 μg/m³ would provide an adequate margin of safety.

In his proposed decision to retain the current primary 24-hour $PM_{2.5}$ standard with a level of 35 μg/m³, the Administrator first considered the scientific information related to short-term exposures to $PM_{2.5}$ and health effects. He noted that the controlled human exposure studies are the strongest line of evidence for informing his conclusions regarding the adequacy of the current 24-hour standard. In so doing, the Administrator recognized that controlled human exposure studies are conducted with healthy adult volunteers and that these studies do not include individuals who may be at increased risk of $PM_{2.5}$-related health effects (*i.e.,* children, older adults, people with pre-existing diseases). He also noted that the effects observed in the controlled human exposure studies (*e.g.,* changes in vascular function) are not effects that are judged to be clearly adverse. He recognized the most consistent evidence of effects in these studies occurs at higher concentrations (*e.g.,* >120 μg/m³) following 1–5 hour exposures, and that one study observed effects at concentrations as low as 38 μg/m³ following 4-hour exposures. However, the Administrator reiterated that these studies do not tell us at exactly what concentrations an adverse effect might occur, especially for at-risk populations. As noted above in section II.A.2.c, controlled human exposure studies tend to include generally healthy adult individuals who are at a lower risk of experiencing health effects, and often do not include at-risk populations (*e.g.,* children, older adults, or individuals with pre-existing conditions). As such, the Administrator recognized that these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in in at-risk populations. The Administrator also considered air quality analyses in the 2022 PA that demonstrate that there will be very few, if any, days with $PM_{2.5}$ concentrations at levels evaluated in controlled human exposure studies that are associated with effects in areas that meet the current primary 24-hour $PM_{2.5}$ standard.

The Administrator also noted that as, in previous PM NAAQS reviews, the protection provided by the suite of standards (*e.g.,* annual and 24-hour standards) is evaluated together. He noted that the annual standard is the controlling standard in most areas of the country. He also considered air quality analyses in the 2022 PA that suggest that revision of the annual standard to a level between 9–10 μg/m³ would also control 24-hour $PM_{2.5}$ concentrations in most areas to, or below, 30 μg/m³. Finally, the Administrator noted the agreement with the advice from the minority of CASAC and additionally noted the limited rationale and evidence provided by the majority CASAC's recommendation to support revision of the 24-hour standard. As such, the Administrator proposed to retain the current 24-hour standard with its level of 35 μg/m³.

Additionally, the Administrator proposed to conclude that it is appropriate to retain all other elements (*i.e.,* indicator, averaging time, and form) of the annual and 24-hour standards.

3. Comments on the Proposed Decision

With respect to the adequacy of the primary annual $PM_{2.5}$ standard, a number of commenters, primarily those from industry and industry groups, non-governmental organizations, and some State and local governments, disagree with the EPA's proposed decision to revise the level of the primary annual $PM_{2.5}$ standard. These commenters generally expressed the view that the current standards provide the requisite degree of public health protection and should be retained, consistent with the 2020 final decision. In supporting their view, these commenters assert that the scientific evidence available in this reconsideration is essentially unchanged since the 2020 final decision and that the additional scientific evidence and quantitative risk information available for the reconsideration does not support strengthening the primary annual $PM_{2.5}$ standard. These commenters also assert that uncertainties associated with the available scientific evidence have not changed since the 2020 final decision, and they note that these uncertainties were essential factors in the then-Administrator's decision to retain the primary annual $PM_{2.5}$ standard. These commenters argue that, while the current Administrator acknowledges these uncertainties, he does not place enough weight on them in reaching his conclusions regarding the current standard. The commenters specifically highlight uncertainties related to exposure misclassification, confounding, and other sources of potential bias, which they claim supports retaining the current level of the annual standard. These commenters also note that these uncertainties were emphasized by the minority of the CASAC in their review of the 2021 draft PA, and the commenters further suggest that the lack of consensus from the CASAC on the appropriate level for the primary annual $PM_{2.5}$ standard show that the research is unclear. The commenters contend that there is not support in this reconsideration for deviating from the then-Administrator's decision in 2020.

In contrast, other commenters, primarily from public health and environmental organizations, some State and local elected representatives, and some State and local government agencies agree with the EPA's proposed decision that the primary annual $PM_{2.5}$ standard is not adequate. These commenters support revising the level of the primary annual $PM_{2.5}$ standard and emphasize that the available scientific evidence, in particular epidemiologic studies, along with the CASAC's advice in their review for the 2021 draft PA, provide strong support for the proposed decision. In particular, these commenters agree with the EPA's conclusions about the strength of the scientific evidence, including uncertainties, and they emphasize that the CASAC reached consensus in their review of the 2021 draft PA that the current primary annual $PM_{2.5}$ standard is not adequate. Some of these commenters also note that a revised primary annual $PM_{2.5}$ standard would result in significant public health benefits by reducing morbidity and mortality associated with $PM_{2.5}$ exposure, especially for at-risk populations.

The EPA agrees with commenters that the primary annual $PM_{2.5}$ standard is not adequate. The EPA recognizes the longstanding body of health evidence supporting relationships between $PM_{2.5}$ exposures (short- and long-term) and both mortality and serious morbidity effects. The evidence available in this reconsideration (*i.e.,* the studies

assessed in the 2019 ISA and ISA Supplement summarized above in section II.A.2.a) reaffirms, and in some cases strengthens, the conclusions from the 2009 ISA regarding the health effects of $PM_{2.5}$ exposures. As noted above, epidemiologic studies demonstrate generally positive and often statistically significant associations between $PM_{2.5}$ exposures and health effects. Such studies report associations between estimated $PM_{2.5}$ exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (*e.g.,* lung cancer mortality or incidence, asthma development). Recent experimental evidence, as well as evidence from epidemiologic panel studies, strengthens support for potential biological pathways through which $PM_{2.5}$ exposures could lead to the serious effects reported in many population-level epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. Moreover, these recent epidemiologic studies strengthen support for health effect associations at $PM_{2.5}$ concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews.

Additionally, as discussed in more detail in section I.C.5.b above, the ISA Supplement focused on studies that were most likely to inform decisions on the appropriate standard, but not to reassess areas that, based on the assessment of available science published since the cutoff date of the 2019 ISA and through 2021, were judged unlikely to have new information that would be useful for the Administrator's decision making. The ISA Supplement included U.S. and Canadian epidemiologic studies for health effect categories where the 2019 ISA concluded a causal relationship (*i.e.,* short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality), as well as U.S. and Canadian epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses (*i.e.,* studies that examined the effect of a policy on reducing $PM_{2.5}$ concentrations). These studies, summarized in section II.A.2.a above, examine both short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality. Additionally, studies that employ alternative methods for confounder control, as described in II.A.2.a above and in Table 3–11 and of the 2022 PA (U.S. EPA, 2022b), use a variety of statistical methods to control for confounding bias. These studies consistently report positive associations, which further supports the broader body of epidemiologic evidence for both cardiovascular effects and mortality.

In addition, there are epidemiologic studies that provide supplemental information for consideration in reaching conclusions that the current suite of $PM_{2.5}$ standards is not adequate. These studies include analyses that restrict annual average $PM_{2.5}$ concentrations to concentrations below 12 $\mu g/m^3$ and provide support for positive and statistically significant associations with mortality and cardiovascular morbidity at mean $PM_{2.5}$ concentrations below the current level of the primary annual $PM_{2.5}$ standard (described above in section II.A.2.c.ii and in Table 3–10 of the 2022 PA (U.S. EPA, 2022b)). Recent accountability studies that have starting annual $PM_{2.5}$ concentrations at or below 12 $\mu g/m^3$ suggest public health improvements may occur at concentrations below 12 $\mu g/m^3$. These studies indicate positive and statistically significant associations with mortality and morbidity (*e.g.,* cardiovascular hospital admissions) and reductions in $PM_{2.5}$ concentrations in ambient air (described above in section II.A.2.c.ii and in Table 3–12 of the 2022 PA (U.S. EPA, 2022b)).

Thus, in considering the available scientific evidence to inform conclusions on the adequacy of the primary $PM_{2.5}$ standards, the Administrator recognizes that the 2019 ISA and the ISA Supplement together provides a strong scientific foundation for concluding that the current primary $PM_{2.5}$ standards are not adequate.

In addition to the scientific evidence above, the risk assessment estimates that the current primary annual $PM_{2.5}$ standard could allow a substantial number of deaths in the U.S. Although the Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, they should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposures and related health effects. The Administrator takes into consideration these uncertainties, which are described in more detail in section II.A.3.b above, but notes that the general magnitude of risk estimates supports the potential for significant public health impacts, particularly for lower alternative annual standard levels.

In the CASAC's review of the 2019 draft PA, the CASAC did not reach consensus on whether the current annual standard is adequate, with the majority of the CASAC recommending that the annual standard be retained and the minority of the CASAC recommending that the standard be revised. In their review of the 2021 draft PA, the CASAC unanimously recommended that the current annual standard is not sufficiently protective of public health (Sheppard, 2022a, p. 2 of consensus letter).

The EPA disagrees with the commenters who state that the available scientific and quantitative information available in this reconsideration does not provide support for the current Administrator to reach a different decision than the then-Administrator reached in the 2020 final action. The EPA agrees with these commenters that there are uncertainties associated with the currently available scientific evidence. The EPA has considered these uncertainties extensively both in reaching conclusions in the 2022 PA (U.S. EPA, 2022b, sections 3.4.3, 3.6.1, and 4.6.3) and in the proposal (88 FR 5604, 5609, January 27, 2023), and the EPA addresses more detailed public comments about these uncertainties, including those related to copollutant confounding, unmeasured confounding, and temporal and spatiotemporal confounding, in the Response to Comments document. However, we disagree with the commenters that the evidence does not provide support for the Administrator's conclusion that the current primary annual $PM_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety, and should be revised. As described above, epidemiologic studies in the 2019 ISA and the ISA Supplement support and extend the evidence evaluated in the 2009 ISA, through studies conducted in diverse populations and geographic locations, using various statistical models and approaches to control for potential confounders, and using a variety of exposure assessment methodologies. Therefore, the consistent, positive associations reported across studies (U.S. EPA, 2019a, Figures 11–1 and 11–18; U.S. EPA, 2022a) are unlikely to be to be the result of unmeasured confounding and other biases are unlikely to account for the consistent positive associations observed across epidemiologic studies.

Additionally, this reconsideration includes epidemiologic studies that were not before the then-Administrator for consideration in reaching his final decisions at the time of the 2020 decision and that specifically evaluate

confounding using alternative methods for confounder control). These recent epidemiologic studies provide support for the current Administrator's conclusion that the suite of primary $PM_{2.5}$ standards are not adequate. While confounding was an uncertainty noted by the then-Administrator in the 2020 decision, he recognized ''that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study'' (85 FR 82710, December 18, 2020). The ISA Supplement considered studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.,* used alternative methods for confounder control),[92] given that such studies were highlighted by the CASAC in their review of the 2019 draft PA and identified in public comments on the 2020 proposal. Since the literature cutoff date for the 2019 ISA, multiple studies that employ alternative methods for confounder control have become available for consideration in the ISA Supplement and, subsequently, in this reconsideration. For example, one study before the Administrator in this reconsideration that was not available in the 2019 ISA is Schwartz et al. (2021), which used a causal modeling approach focused on exposure changes and controls for measured confounders by design in order to evaluate the association between long-term $PM_{2.5}$ exposure and mortality in the Medicare population. The study authors found significant associations of $PM_{2.5}$ with increased mortality rates using a causal modeling approach robust to omitted confounding. The results of this study and other studies in the ISA Supplement that employ alternative methods to control for confounders lend support to the robustness of positive associations between $PM_{2.5}$ exposure and multiple morbidity and mortality endpoints exhibited across epidemiologic studies, and also indicate that unmeasured confounding and other biases are unlikely to account for the consistent positive associations observed across epidemiologic studies (U.S. EPA, 2022b, sections 3.1.1.3, 3.1.2.3, 3.2.1.3, and 3.2.2.3).

Further, the EPA disagrees with the commenters who argue that the Administrator did not appropriately consider the strengths and limitations of the health evidence in reaching his decision to revise the current primary annual $PM_{2.5}$ standard in this reconsideration. In reaching his proposed decision, the Administrator considered the entire body of evidence and how to appropriately weigh the uncertainties associated with the health evidence (88 FR 5617, January 27, 2023). Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that ''Congress provided that the Administrator is to use his judgment in setting air quality standards precisely to permit him to act in the face of uncertainty,'' the Administrator must set standards on ''the frontiers of scientific and medical knowledge'' and ''Congress directed the Administrator to err on the side of caution in making the necessary decisions.'' *Lead Indus. Ass'n, Inc.* v. *EPA,* 647 F.2d 1130, 1155 & n.50 (D.C. Cir. 1980) (quoting H.R. Rep. No. 95–294, at 50). As such, a determination of identifying a specific level at which the standard should be set necessarily requires the Administrator's judgement (*e.g.,* weighing the uncertainties and margin of safety).

Additionally, the EPA disagrees with the commenters that contend that there is no basis in this reconsideration for deviating from the previous Administrator's decision in 2020. It is well-established that in CAA section 109 Congress specifically left the determination of the requisite NAAQS to the judgment of the Administrator and, moreover, that ''decisions about the appropriate NAAQS level must 'necessarily . . . rest largely on policy judgments.' '' *Mississippi* v. *EPA,* 744 F.3d 1344, 1357 (D.C. Cir. 2013) (quoting *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1147 (D.C. Cir. 1980)). As the Court of Appeals for the D.C. Circuit has noted, ''Every time EPA reviews a NAAQS, it (presumably) does so against contemporary policy judgments and the existing corpus of scientific knowledge.'' *Id.,* at 1343.

In this reconsideration, both the existing corpus of scientific knowledge as well as the Administrator's policy judgments about how to interpret and weigh that evidence to protect public health with an adequate margin of safety have changed. The expansion of the air quality criteria to encompass additional studies, information and analyses in the ISA Supplement and 2022 PA, as well as the additional consideration of the scientific record by the CASAC and the public provided the Administrator with significant additional information on which to base his decision.[93] In addition, in this reconsideration, the Administrator is reaching different judgments about how to weigh the epidemiologic evidence, including the uncertainties in the scientific evidence, and how to ensure an adequate margin of safety to protect against uncertain harms, compared to the approach in the 2020 final decision. For example, as discussed in greater detail above in section II.A.1 and in the 2020 notice of final rulemaking (85 FR 82717, December 18, 2020), in considering the epidemiologic evidence as part of his decision to retain the current primary annual $PM_{2.5}$ standard in the 2020 decision, the then-Administrator placed weight on the mean of the study-reported means (or medians) (*i.e.,* 13.5 $\mu g/m^3$) from key U.S. epidemiologic studies that are monitor-based being above the level of the current primary annual $PM_{2.5}$ standard of 12.0 $\mu g/m^3$. By contrast, in this reconsideration, the current Administrator has taken an approach more similar to how the EPA has considered study-reported mean $PM_{2.5}$ concentrations relative to the level of the primary annual $PM_{2.5}$ standard in other recent PM NAAQS reviews. In so doing, in reaching his decision to revise the level of the primary annual $PM_{2.5}$ standard to 9.0 $\mu g/m^3$, he is using an approach that places weight on selecting a level for the standard that is below the study-reported mean $PM_{2.5}$ concentrations reported in key U.S. epidemiologic studies, including recent epidemiologic studies that use hybrid model-based methods, as well as being near or below the 25th percentile $PM_{2.5}$ concentrations in those key U.S. epidemiologic studies that report these concentrations.

As such and further detailed in section II.B.4 below, in considering the adequacy of the current primary PM standards in this reconsideration, the Administrator has carefully considered the: (1) Policy-relevant evidence and conclusions contained in the 2019 ISA and 2022 ISA Supplement; (2) the quantitative information presented and

[92] As noted in the ISA Supplement: ''In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling methods. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.,* the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence'' (U.S. EPA, 2022a, p. 1–3).

[93] The EPA notes that, in considering the additional scientific evidence available in this reconsideration, one member of the CASAC who reviewed both the 2019 draft PA and the 2021 draft PA found that the available scientific and quantitative information available in this reconsideration supported revising the level of the primary annual $PM_{2.5}$ standard, whereas he recommended retaining the standard during the review of the 2019 draft PA.

assessed in the 2022 PA; (3) the evaluation of this evidence, the quantitative information, and the rationale and conclusions presented in the 2022 PA; (4) the advice and recommendations from the CASAC; and (5) public comments. The Administrator concludes that the current suite of primary $PM_{2.5}$ standards are not adequate to protect public health with an adequate margin of safety.

The four basic elements of the NAAQS (indicator, averaging time, form, and level) are considered collectively in evaluating the health protection afforded by a standard. The EPA received relatively few comments on the averaging time and form for the primary $PM_{2.5}$ standards, but those who did provide comments on these elements were primarily from public health and environmental organizations, State and local elected representatives, and State and local government agencies. Some commenters assert that the current 24-hour averaging time for the primary 24-hour $PM_{2.5}$ standard does not adequately protect against short-term peaks. These commenters further state that the 24-hour averaging time protects against chronic exposures but does not adequately protect against serious acute risks from certain sources such as prescribed burning. Also, a few commenters explicitly recommend that a subdaily averaging time would be more appropriate, although none of the commenters recommended a specific averaging time for consideration. Additionally, some commenters cite to the CASAC's advice in their review of the 2021 draft PA that future reviews of the PM NAAQS should include evaluation of alternative forms and averaging times of the current primary 24-hour $PM_{2.5}$ standard.

The EPA disagrees with commenters that the current primary 24-hour $PM_{2.5}$ standard, with its 24-hour averaging time, does not adequately protect against short-term peaks and disagrees that that there is sufficient information to conclude that a subdaily averaging time would be more appropriate than a 24-hour averaging time. The EPA has reviewed the currently available scientific evidence and finds that it does not indicate that alternative averaging times would be more appropriate for the primary $PM_{2.5}$ standards. Accordingly, the EPA concludes that it is appropriate to retain both the annual and 24-hour averaging times for standards meant to protect against long- and short-term $PM_{2.5}$.

As noted in the proposal, the 2019 ISA and ISA Supplement found that the scientific evidence continues to provide strong support for health effect associations with both long-term (*e.g.,* annual or multi-year) and short-term (*e.g.,* mostly 24-hour) exposures to $PM_{2.5}$. Epidemiologic studies continue to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour $PM_{2.5}$ averaging periods, and we note that subdaily effect estimates are less consistent and, in some cases, smaller in magnitude (88 FR 5618, January 27, 2023). Controlled human exposure and panel-based studies of subdaily exposures typically examine subclinical effects rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.,* mortality, hospitalizations). Collectively, the 2019 ISA concludes that epidemiologic studies do not indicate that subdaily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, the EPA notes that while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (*i.e.,* <30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2022a, section 3.3.3.1). Therefore, this information does not indicate that a revision to the averaging time is needed to provide additional protection against subdaily $PM_{2.5}$ exposures, beyond that provided by the current primary standards. This conclusion is also supported by the advice given to EPA by the CASAC in their review of the 2021 draft PA, which reached consensus that averaging times for the standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[94] For all of these reasons, the Administrator concludes that the currently available evidence does not support considering alternatives to the annual and 24-hour averaging times for standards meant to protect against long- and short-term $PM_{2.5}$ exposures.

Multiple commenters, primarily from public health and environmental organizations, recommend revising the form of the primary 24-hour $PM_{2.5}$ standard to a 99th percentile to provide increased public health protection against peak $PM_{2.5}$ exposures, particularly for at-risk populations. These commenters express concern that the current 98th percentile form allows 7 exceedances per year and contend that a 99th percentile form that would allow half that number is more appropriate. Commenters also cite to the CASAC's advice in their review of the 2021 draft PA, which recommended that the EPA consider alternative percentiles for the form of the primary 24-hour $PM_{2.5}$ standard in the future.

The EPA disagrees that the current 98th percentile form does not provide the requisite public health protection against peak $PM_{2.5}$ exposures and concludes that the 98th percentile, averaged over three years, remains appropriate for the primary 24-hour $PM_{2.5}$ standard. As noted in previous reviews and in the proposal, the EPA has set both an annual standard and a 24-hour standard to provide protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$ (62 FR 38667, July 18, 1997; 88 FR 5620, January 27, 2023). With respect to the form of the 24-hour standard, as described just above, the epidemiologic studies continue to provide strong support for health effect associations with short-term (*e.g.,* mostly 24-hour) $PM_{2.5}$ exposures and controlled human exposure studies provide evidence for health effects following single short-term ''peak'' $PM_{2.5}$ exposures (88 FR 5619, January 27, 2023). Both the 98th and the 99th percentile form provide a very high degree of control of peak concentrations. As the commenters point out, a 99th percentile would reduce the number of allowable exceedances to four days per year. The EPA anticipates, however, that such a revision to the form would make the attainment status of an area more subject to change from unpredictable nonanthropogenic factors, such as meteorological events. The EPA has often noted that frequent shifts in attainment status that are unrelated to long-term air quality trends is inconsistent with providing a stable target for air quality planning and risk management programs, which in turn provides for the most effective public health protection in the long run (78 FR 3127, January 15, 2013; 80 FR 65351, October 26, 2015). Thus, the EPA's interest in an appropriate degree of stability is to ensure that the State air quality programs are effective in controlling pollution and that the public health protections of the standard are achieved. As discussed above, while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following $PM_{2.5}$

[94] In providing advice on the 2019 draft PA, the CASAC did not weigh in specifically on the averaging time of the primary 24-hour $PM_{2.5}$ standard but did recommend that the standard be retained because the available evidence does not call into question its adequacy (Cox, 2019b, p. 3 of consensus letter).

exposures for less than 24 hours (*i.e.,* < 30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2022a, section 3.3.3.1), and the 98th percentile form is very effective at limiting occurrences of exposures of concern. Taking into consideration the available scientific information and quantitative information, the EPA therefore concludes that the 98th percentile form provides an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs. This conclusion is also supported by the advice given to the EPA by the CASAC in their review of the 2021 draft PA, where they reached consensus that the form for the standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[95]

Additionally, the EPA recognizes the CASAC's advice in their review of the 2021 draft PA, where they recommended ''that in future reviews, the EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level'' (Sheppard, 2022a, p. 4 of consensus letter). This advice is reflected in the proposal by the EPA, which noted ''that it would be appropriate to gather additional air quality and scientific information and further consider these issues in future reviews'' (88 FR 5619, January 27, 2023). The EPA will consider the information provided by the commenters regarding the form of the 24-hour $PM_{2.5}$ standard in the next review of the PM NAAQS.

A number of commenters who support revising the level of the primary annual $PM_{2.5}$ standard, particularly those who support a revised level of 8 $\mu g/m^3$, disagree with how the EPA has emphasized the mean $PM_{2.5}$ concentrations reported in key epidemiologic studies to inform conclusions on the level of the primary $PM_{2.5}$ standard. These commenters argue that, in this reconsideration, the EPA is arbitrarily emphasizing uncertainties in key epidemiologic studies in the focus on mean concentrations. Many of these commenters recommend that the EPA consider the full distribution of $PM_{2.5}$ concentrations from the key epidemiologic studies in reaching conclusions on the appropriate level for the primary annual $PM_{2.5}$ standards, in particular concentrations below the mean, such as the 25th percentile. In supporting this view, commenters point to the CASAC's advice in their review of the 2021 draft PA, where the majority of the CASAC stated that the ''use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration-response functions'' (Sheppard, 2022a, p. 16 of consensus responses), and that ''[e]pidemiologic studies require consideration of distribution around the mean of exposure to identify effects and thus lower levels than the mean must be considered as part of the range where the data provide higher confidence'' (Sheppard, 2022a, p. 13 of consensus responses).

As an initial matter, consistent with some previous approaches and as detailed by the Administrator in reaching conclusions on the level of the primary annual $PM_{2.5}$ standard in section II.B.4 below, the EPA considers the long-term study-reported mean $PM_{2.5}$ concentrations from key epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean $PM_{2.5}$ concentration. Additionally, as discussed further below, the EPA also considers the available information from a subset of epidemiologic studies that report exposure estimates or health events at the 25th and 10th percentiles of $PM_{2.5}$ concentrations. The Administrator gives some weight to the 25th percentile data, although he recognizes that his confidence in the magnitude and significance in the reported concentrations, and their ability to inform decisions on the appropriate level of the annual standard, decreases with reduced data (below the mean) and diminishes further at percentiles that are even further below the mean and the 25th percentile. Therefore, the Administrator places weight on the reported 25th percentiles concentrations, rather than the reported 10th percentile concentrations, for the subset of studies that report lower percentile $PM_{2.5}$ concentrations in reaching his conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard.

In considering the available scientific evidence to reach decisions on the adequacy of the suite of primary $PM_{2.5}$ standards, the EPA notes that in previous PM NAAQS reviews (including the 1997, 2006 and 2012 reviews), evidence-based approaches were used that focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by the CASAC in previous reviews and were supported in this reconsideration by the CASAC in their review of the 2021 draft PA.[96]

In considering the available scientific evidence, the EPA notes the strength of the epidemiologic evidence which includes multiple studies that consistently report positive associations for short- and long-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. Some available studies also use a variety of statistical methods to control for confounding bias and report similar associations, which further supports the broader body of epidemiologic evidence for both mortality and cardiovascular effects. Additionally, the EPA notes that recent epidemiologic studies strengthen support for health effect associations at $PM_{2.5}$ concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews.

While these epidemiologic studies evaluate associations between distributions of ambient $PM_{2.5}$ concentrations and health outcomes, they do not identify the specific exposures that led to the reported effects. As such, there is no specific point in the air quality distribution of any epidemiologic study that represents a ''bright line'' at and above which effects have been observed and below which effects have not been observed.

Studies of daily $PM_{2.5}$ exposures examine associations between day-to-day variation in $PM_{2.5}$ concentrations and health outcomes, often over several years. While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with

[95] The CASAC did not provide advice or recommendations regarding the forms of the primary $PM_{2.5}$ standards in their review of the 2019 draft PA (Cox, 2019b).

[96] The Administrator notes that, in their review of the 2021 draft PA, a majority of members of the CASAC noted that there are some limitations for this approach ''for the purpose of informing the adequacy of the standards'' (Sheppard, 2022a, p. 8 of consensus responses) and advised that future reviews should include evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies and in analyses restricting concentrations to below the current standard level. The Administrator also notes that, in their review of the 2019 draft PA, the CASAC lacked consensus on the inferences to be drawn from the epidemiologic evidence, with a majority of CASAC having concerns about confounding, error and bias and concluding that newer studies did not provide a basis for revising the current standards, while a minority concluded that the evidence, including more recent studies showing associations in areas with average long-term $PM_{2.5}$ concentrations below the current annual standard, supported their conclusion that the current standards are inadequate (Cox, 2019b, pp. 8–9 of consensus responses).

ambient $PM_{2.5}$ concentrations around the middle of the air quality distributions examined (*i.e.,* ''typical'' days rather than days with extremely high or extremely low concentrations). Similarly, for studies of annual $PM_{2.5}$ exposures, most of the health events occur at estimated exposures that reflect annual average $PM_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Therefore, in the absence of discernible thresholds, long-term study-reported means—that is, the study-reported ambient $PM_{2.5}$ concentrations in the epidemiologic studies that reflect estimated exposures with a focus around the middle portion of the $PM_{2.5}$ air quality distribution where the bulk of the observed data reside—provide the strongest support for reported health effect associations in epidemiologic studies.

Based on the air quality criteria for this reconsideration, as described in the 2019 ISA, ISA Supplement, 2022 PA and the proposal, the EPA believes it is appropriate to continue to use the mean $PM_{2.5}$ concentrations from the key epidemiologic studies to inform conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard.

There are a large number of key epidemiologic studies available in this reconsideration to inform conclusions regarding the level of the primary annual $PM_{2.5}$ standard. For the key U.S. epidemiologic studies, the study-reported mean $PM_{2.5}$ concentrations range from 9.9–16.5 $\mu g/m^3$ for monitor-based studies (Figure 1 above) and range from 9.3–12.2 $\mu g/m^3$ for hybrid modeling-based studies (Figure 2 above).

In addition to the study-reported mean $PM_{2.5}$ concentrations, the EPA agrees with the CASAC's advice in their review of the 2021 draft PA and public comments that information on other percentiles below the mean can also be informative, and the EPA notes that the CASAC advised that for the purpose of informing the adequacy of the standards, future reviews should include an evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies (Sheppard, 2022a, p. 9 of consensus responses). As such, in reaching conclusions in this reconsideration, the EPA takes note of the additional study-reported $PM_{2.5}$ concentrations below the means (*e.g.,* 25th and 10th percentiles) that are available from a limited subset of key U.S. epidemiologic studies. As shown in Figures 1 and 2 above, six key U.S. epidemiologic studies report information on other percentiles (*e.g.,* 10th and 25th percentiles of $PM_{2.5}$ concentrations or 10th and 25th percentiles of $PM_{2.5}$ concentrations associated with health events) that are below the mean.[97] Three of the studies are monitor-based and three are hybrid model-based.

The key U.S. epidemiologic studies that report percentiles below the mean that are monitor based are older studies. These studies included smaller numbers of people than the newer hybrid model-based studies. For the three older, monitor-based studies, because the cohorts were smaller in size, a relatively smaller portion of the health events were observed in the lower part of the air quality distribution. As such, our confidence in the magnitude and significance of the associations begins to decrease in the lower part of the air quality distribution of those older, monitor-based studies.

The three newer, hybrid model-based studies have larger cohort sizes than the older, monitor-based studies and, as noted by commenters, have more health events in the lower part of the air quality distribution. For these reasons, the EPA notes that we have more confidence in the reported association at concentrations lower than the reported mean in these more recent hybrid model-based studies, particularly at the 25th percentile compared to the 10th percentile. While the cohort sizes in the more recent, hybrid model-based studies are larger than the older, monitor-based studies, the EPA notes that the 10th percentiles are well below the middle portion of the air quality distribution for which we have the greatest confidence, and as noted above, our confidence in the magnitude and significance of associations in the lower parts of the air quality distribution begins to decrease. While we have more confidence in the lower percentiles because of the larger cohort sizes in the more recent hybrid model-based studies, we also have more confidence in the 25th percentiles than in the 10th percentiles, which are further from the means and closer to the lower end of the air quality distribution.

In considering how the six studies that report percentiles lower than the mean can be used to inform conclusions regarding the level of the primary annual $PM_{2.5}$ standard, the EPA first notes that the three monitor-based epidemiologic studies (Bell et al., 2008; Franklin et al., 2007; Zanobetti and Schwartz, 2009) report 25th percentile concentrations that are at or above 11.5 $\mu g/m^3$. For two of the more recent hybrid model-based studies (Di et al., 2017b; Wang et al., 2017), the 25th percentile of estimated $PM_{2.5}$ concentrations are just above 9 $\mu g/m^3$, while one study (Di et al., 2017a) reports a $PM_{2.5}$ concentrations corresponding to 25th percentiles of health events of just below 7 $\mu g/m^3$. For the Di et al. (2017a) study, the 25th percentile $PM_{2.5}$ concentration (6.7 $\mu g/m^3$) is based on the $PM_{2.5}$ concentration at which the 25th percentile of deaths occur in the study, while the reported mean (11.6 $\mu g/m^3$) is based on estimated $PM_{2.5}$ exposure concentrations. Additionally, the 25th percentiles of the other two recently available hybrid model-based studies (Di et al., 2017b; Wang et al., 2017) are based on estimated $PM_{2.5}$ concentrations. As such, the $PM_{2.5}$ concentration at which the 25th percentile of health events occur may be different from the estimated 25th percentile $PM_{2.5}$ concentration in this study (Di et al., 2017a), creating an uncertain basis for comparison with the studies by Di et al. (2017b) and Wang et al. (2017). The 25th percentiles from these studies, in particular those that are more recently available, help to inform the Administrator's judgments regarding the appropriate level for the primary annual $PM_{2.5}$ standard.

Some commenters disagree with the EPA's consideration of the relationship between mean $PM_{2.5}$ concentrations reported in the key epidemiologic studies and design values to inform conclusions on the appropriate level for the primary annual $PM_{2.5}$ standards. Commenters contend that setting the level of the primary annual standard below the design values in the epidemiologic studies, rather than below the study-reported mean concentrations, might keep overall mean $PM_{2.5}$ concentrations throughout an area below the study-reported means but allow $PM_{2.5}$ concentrations in some parts of the area, including near the ''design value monitor'' to remain above the study-reported mean $PM_{2.5}$ concentrations, which are the concentrations where the evidence of health effects is strongest. Commenters contend that such a decision framework would not result in a standard that would provide requisite protection with an adequate margin of safety,

[97] The Wang et al. (2017) study only reports the 25th percentile of the estimated $PM_{2.5}$ concentrations, not the 10th percentile.

particularly for at-risk populations. These commenters further support this view by citing the CASAC's advice in their review of the 2021 draft PA, where the majority of CASAC stated that ''even if a design value is somewhat higher than the area average, it reflects actual exposure levels and thus any portion of the population living near the design value monitor does experience exposures at that level and consequent health effects of exposure to that higher concentration'' (Sheppard, 2022a, p. 14 of consensus responses). Additionally, these commenters suggest that the EPA should not deviate from the approach taken in the 2012 review, which was to set the standard at a level ''somewhat below'' the lowest mean $PM_{2.5}$ concentration in the key epidemiologic studies.

To the extent that commenters are suggesting that the EPA is setting the level of the primary annual $PM_{2.5}$ standard below the design values in the epidemiologic studies, rather than below the study-reported mean $PM_{2.5}$ concentrations, we disagree with the commenters. In reaching conclusions on the level of the primary annual $PM_{2.5}$ standard, the EPA considers the long-term study-reported mean $PM_{2.5}$ concentrations from key epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean $PM_{2.5}$ concentration, not below the design values in the epidemiologic studies. Additionally, the EPA also considers the available information from a subset of epidemiologic studies that report exposure estimates or health events at the 25th and 10th percentiles of $PM_{2.5}$ concentrations. The EPA particularly considers the 25th percentile data, while recognizing that our confidence in the magnitude and significance in the reported concentrations, and the ability of the lower percentile $PM_{2.5}$ concentrations to inform decisions on the appropriate level of the annual standard, decreases with reduced data (below the mean) and diminishes further at percentiles that are even further below the mean and the 25th percentile.

However, the EPA notes that it is important to understand, and to not ignore, the relationship between the study-reported mean $PM_{2.5}$ concentrations reported in key epidemiologic studies and the area design value. As an initial matter, the NAAQS consists of all four elements of the standard (indicator, averaging time, form, and level) and setting a standard that is requisite to protect public health includes consideration of all four elements together. Following implementation of the NAAQS, the design value is the metric used to determine compliance with the standard and is the statistic that describes the air quality status of a given location relative to the level of the primary annual $PM_{2.5}$ NAAQS. The design value is different from the study-reported mean $PM_{2.5}$ concentrations. This is because the study-reported mean $PM_{2.5}$ concentrations are an annual average $PM_{2.5}$ concentration, similar to the level of the standard, but the epidemiologic studies do not report statistics that take into account the other elements of the standard (*i.e.,* averaging time and form). Therefore, when considering the appropriate revisions to the annual $PM_{2.5}$ standard, the EPA must consider the protection provided by a revised standard taking into account all of the elements of the standard, not just the annual average $PM_{2.5}$ concentration alone.

In considering the annual standard, and in assessing the range of study-reported exposure concentrations for which we have the strongest support for adverse health effects observed in epidemiologic studies, the EPA focuses on whether the current primary annual $PM_{2.5}$ standard provides adequate protection against these exposure concentrations or if the level of the standard should be revised to provide the appropriate public health protection. This means that, as in some previous reviews, it is important to consider how the study means were computed and how these concentrations compare to the annual standard metric (including the level, averaging time and form) which must be met at the monitor with the highest $PM_{2.5}$ design value in an area for compliance with the NAAQS. This approach is based on the application of a decision framework based on assessing means (as well as the lower distribution of reported $PM_{2.5}$ concentration, as noted above) reported in key epidemiologic studies. In the 2012 review, the available key epidemiologic studies computed the mean $PM_{2.5}$ concentrations using an average across monitor-based $PM_{2.5}$ concentrations. As such, at that time, the decision framework used an approach based on maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations (*i.e.,* selecting the standard level of 12.0 μg/m^3 was just below the long-term study-reported mean $PM_{2.5}$ concentrations in key epidemiologic studies). Further, the EPA conducted analyses that examined the differences in these two metrics (*i.e.,* maximum monitor concentrations, which is how compliance with the standard is assessed and composite monitor concentrations, which is how key epidemiologic studies report their mean concentrations) across the U.S. and in areas included in the key epidemiologic studies and found that the maximum design value in an area was generally higher than the monitor average across that area, with the amount of difference between the two metrics varying based on location and concentration (Hassett-Sipple et al., 2010; Frank, 2012). This information was taken into account by the then-Administrator's final decision in selecting a level of 12.0 μg/m^3 for the primary annual $PM_{2.5}$ standard in the 2012 review and discussed more specifically in her considerations on adequate margin of safety.

The relationship between the mean $PM_{2.5}$ concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative annual standard levels in this reconsideration. Again, in a given area, the area design value is based on the monitor in an area with the highest $PM_{2.5}$ concentrations and is used to determine compliance with the standard, including the averaging time and form of the standard (*i.e.,* an annual average over 3-years must not exceed the level of the of the annual $PM_{2.5}$ standard). The highest $PM_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and the distribution of $PM_{2.5}$ concentrations would generally be lower in other locations and at monitors in that area. As such, when an area is meeting a specific annual standard level (*e.g.,* 9.0 μg/m^3), we would expect the annual average exposures (*i.e.,* a metric similar to the study-reported mean values) in that area to be at concentrations lower than that level (*e.g.,* lower than 9.0 μg/m^3).

However, as described in section II.A.2.c.ii, we note that there are a substantial number of different types of epidemiologic studies available since the 2012 review, as assessed in both the 2019 ISA and the ISA Supplement, that make understanding the relationship between the mean $PM_{2.5}$ concentrations and the area design value an even more important consideration in this reconsideration (U.S. EPA, 2019a; U.S. EPA, 2022a). While the key epidemiologic studies in the 2012 review were all monitor-based studies, the recent epidemiologic studies in this reconsideration include hybrid modeling approaches that have emerged in the epidemiologic literature as an

alternative to approaches that only use ground-based monitors to estimate $PM_{2.5}$ exposure. As assessed in the 2019 ISA and ISA Supplement, a substantial number of epidemiologic studies used hybrid model-based methods in evaluating associations between $PM_{2.5}$ exposure and health effects. Hybrid model-based studies employ various fusion techniques that combine ground-based monitored data with air quality modeled estimates and/or information from satellites to estimate $PM_{2.5}$ exposures. While these studies provide a broader estimation of $PM_{2.5}$ exposures compared to monitor-based studies (*i.e.,* $PM_{2.5}$ concentrations are estimated in areas without monitors), the hybrid modeling approaches result in study-reported means that are more difficult to relate to the annual standard metric and to the maximum monitor design values used to assess compliance. In addition, to further complicate the comparison, when looking across these studies, we find variations in how exposure is estimated between such studies, and thus, how the study means are calculated. Two important variations across studies include: (1) Variability in spatial scale used (*i.e.,* averages computed across the national (or large portions of the country) versus a focus on only CBSAs); and (2) variability in exposure assignment methods (*i.e.,* averaging across all grid cells, averaging across a scaled-up area like a ZIP code, and population weighting). The differences in these approaches can result in studies reporting different study means, even though the association between $PM_{2.5}$ exposure and health effects outcomes are similar.

To emphasize the importance of the differences between the studies, we revisit the simplified example in the State of Georgia from the 2022 PA that evaluates monitors and hybrid modeling approaches, noting that this example is useful to exhibit how the differences in the methods used to estimate exposure can lead to differences in the reported mean concentrations (U.S. EPA, 2022b, p. 3–71). In this example, for all monitors within the Atlanta-Sandy Springs-Roswell CBSA, the average $PM_{2.5}$ concentration is 9.3 $\mu g/m^3$, while the area design value (based on the highest monitored $PM_{2.5}$ concentration in the area) is 10.4 $\mu g/m^3$. This comparison helps to illustrate the fact that composite monitor values tend to be somewhat lower than the highest area monitor values, consistent with the key points made in the 2012 review. This example also illustrates how monitors are sited to represent the higher concentrations within the area and that the area's annual design value, which is used for compliance with the standard, is calculated based on the highest monitor in the area. Next, in this example, mean $PM_{2.5}$ concentrations were calculated using similar approaches to those used in hybrid modeling-based epidemiologic studies to compute study-reported means, including (1) the average concentration across the entire State of Georgia; (2) the population-weighted average across the entire State; (3) the average concentration across the Atlanta-Sandy Springs-Roswell CBSA; and (4) the population-weighted average across the Atlanta-Sandy Springs-Roswell CBSA. At the urban level (*e.g.,* Atlanta-Sandy Springs-Roswell CBSA), the average $PM_{2.5}$ concentration when taking the mean of all grid cells is 9.2 $\mu g/m^3$, whereas the population-weighted mean is 9.6 $\mu g/m^3$. Across Georgia, the average $PM_{2.5}$ concentration using the hybrid approach and averaged across each grid cell is 8.3 $\mu g/m^3$, which is lower than the population-weighted statewide average of 9.1 $\mu g/m^3$. While this is a simple example completed in one State and one CBSA, it suggests that the lowest mean values tend to result from the approaches that use concentrations from all or most grid cells (*e.g.,* did not apply population weighting), both urban and rural, across the study area to compute the mean. Higher mean values are observed when the approach focuses on the urban areas alone or when the approach incorporates population weighting. Overall, this example suggests that the means from studies using hybrid modeling approaches are generally lower than the means from monitor-based approaches, and means from both approaches are lower than the annual design values for the same area. Population weighting tends to increase the calculated mean concentration, likely because more densely populated areas also tend to have higher $PM_{2.5}$ concentrations. In other words, this simplified example exhibits how not all reported mean $PM_{2.5}$ concentrations from key epidemiologic studies are the same; some reported means are from monitored studies and some reported means are from hybrid modeling studies, while some reported means include only urban areas, and other reported means include both urban and rural areas, and some reported means include aspects of population weighting while others do not.

As detailed above in section I.D.5, in the air quality analyses comparing composite monitored $PM_{2.5}$ concentrations with annual $PM_{2.5}$ design values in U.S. CBSAs, maximum annual $PM_{2.5}$ design values were approximately 10% to 20% higher than annual average composite monitor concentrations (*i.e.,* averaged across multiple monitors in the same CBSA). Based on these results, this analysis suggests that there will be a distribution of concentrations and the maximum annual average monitored concentration in an area (at the design value monitor, used for compliance with the standard), will generally be 10–20% higher than the average across the other monitors in the area. Thus, in considering how the annual standard levels would relate to the study-reported means from monitor-based studies, we can generally conclude that an annual standard level that is no more than 10–20% higher than monitor-based study-reported mean $PM_{2.5}$ concentrations would generally maintain air quality exposures to be below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring.

Air quality analyses described in section I.D.5 above also consider information from the epidemiologic studies that utilized the hybrid modeling approaches. Analyses show that average maximum annual design values are 40–50% higher when compared to annual average $PM_{2.5}$ concentrations estimated without population weighting and are 15–18% higher when compared to average annual $PM_{2.5}$ concentrations with population weighting applied. Given these results, it is worth noting that for the studies using the hybrid modeling approaches, the choice of methodology employed in calculating the study-reported means (*i.e.,* using population weighting versus not applying aspects of population weighting), and not a difference in estimates of exposure in the study itself, can produce substantially different study-reported mean values, with the approach that does not employ population weighting producing a much lower reported mean $PM_{2.5}$ concentration. Therefore, the impact of the differences in methods is an important consideration when comparing mean concentrations across studies.

Because of the differences in the methods employed by the key epidemiologic studies, and as demonstrated by the example and air quality analyses above, the application of any decision framework that considers the study-reported mean $PM_{2.5}$ concentrations, and evaluates whether the current annual standard provides adequate protection against these reported exposure concentrations, is more complicated than the

approaches used in past reviews. As such, the EPA disagrees with commenters who argue that the EPA's consideration of the relationship between mean $PM_{2.5}$ concentrations reported in key epidemiologic studies and design values is not appropriate and should be ignored.

In considering the information from the epidemiologic studies, while the EPA does not dispute the reported associations of epidemiologic studies in hybrid modeling studies that report long-term mean concentrations and do not apply aspects of population weighting, using the reported long-term mean concentration from these studies in informing an appropriate level of the annual $PM_{2.5}$ standard is more uncertain. Given this, hybrid modeling studies that do not apply aspects of population weighting provide less information on conclusions regarding the appropriate level of the primary annual $PM_{2.5}$ standard. In support of this, some commenters also noted this consideration and suggested that the Administrator place lower weight on U.S. studies that did not use population weighting.

In considering the relationship between study-reported mean $PM_{2.5}$ concentrations and the design values, the EPA agrees with commenters that setting the level of the primary annual standard below the design values, rather than below the study-reported mean concentrations, might allow $PM_{2.5}$ concentrations in some part of the area near the design value monitor to remain above the study-reported mean $PM_{2.5}$concentration, where evidence of health effects is strongest. As discussed in the proposal and in section II.B.4 below, the Administrator specifically notes that that the highest $PM_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and that $PM_{2.5}$ concentrations will be equal to or lower at other monitors in the area. Furthermore, since monitoring strategies aim to site monitors in areas with higher $PM_{2.5}$ concentrations, monitored areas will generally have higher concentrations compared to areas without monitors. Therefore, by setting the level of the standard to 9.0 $\mu g/m^3$ and just below the lowest study-reported mean $PM_{2.5}$ concentration (*e.g.,* 9.3 $\mu g/m^3$), the highest possible design value in a given area would be just below the study-reported mean $PM_{2.5}$ concentration, the concentration where we have the most confidence in the reported health effect association, and we anticipate that, based on our assessment of air quality data, the distribution of $PM_{2.5}$ concentrations would decrease even further with distance from the highest monitor (*i.e.,* the ''design value monitor'') (see, for example, U.S. EPA, 2022a, section 2.3.3.2.4 and pp. 3–71 to 3–77). The Administrator further notes that when an epidemiologic study reports a mean $PM_{2.5}$ concentration that reflects the average of annual average monitor-based concentrations across an area, the area design value will generally be higher than the study-reported mean. Similarly, he observes that when a study reports a mean that reflects the average of annual average concentrations estimated at across an area using a hybrid modeling approach, the area design value will generally be higher. As such, by evaluating the difference between the study-reported mean $PM_{2.5}$ concentrations and design values, the Administrator seeks to set the level of the standard below the lowest study-reported mean, while ensuring that the primary annual $PM_{2.5}$ standard, including its averaging time and form, provides protection against the exposures associated with health effects observed in the key epidemiologic studies.

Additionally, the EPA disagrees with commenters who contend that the approach taken may allow $PM_{2.5}$ near the design value monitor to remain above the study-reported mean $PM_{2.5}$ concentrations. In following this approach of setting the annual standard level somewhat below the lowest reported mean $PM_{2.5}$ concentration, setting a standard level that requires the design value monitor (which is the highest monitor in an area) to be just below the lowest study-reported mean across key studies will generally result in distributions of even lower concentrations of $PM_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where $PM_{2.5}$ concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the $PM_{2.5}$ concentrations reported in the epidemiologic studies where there is the highest confidence of an association. In their review of the 2021 draft PA, the majority of the CASAC had some concerns about the approach for comparing study means and design values, questioning whether such an approach would provide adequate protection for people who live in areas with higher concentrations, such as those living in areas with higher concentrations (*e.g.,* near the design value monitor) (Sheppard, 2022a, p. 8 of consensus responses). The minority of the CASAC, in considering the relationship between the study-reported mean $PM_{2.5}$ concentration and design values, stated that ''the form of the standard and the way attainment with the standard is determined (*i.e.,* highest design value in the CBSA) are important factors when determining the appropriate level for the standard'' and noted that that design values are generally higher than area average exposure levels (Sheppard, 2022a, p. 17 of consensus responses). For all of the reasons discussed above, and consistent with the minority of the CASAC's advice in their review of the 2021 draft PA, we disagree with the commenters that areas near the design value monitors would be expected to experience $PM_{2.5}$ concentrations above the study-reported mean concentrations.

Several commenters assert that epidemiologic studies that restrict $PM_{2.5}$ concentration to below 12 $\mu g/m^3$ provide additional support for revising the level of the primary annual $PM_{2.5}$ standard to 8 $\mu g/m^3$. Some commenters disagree with the EPA's assertion that the studies that employ restricted analyses do not provide enough information to understand how the studies were restricted to certain $PM_{2.5}$ concentrations, with commenters providing additional information on the methods for restricted analyses. The commenters state that for the long-term studies at issue here, the study authors simply examined their database that linked subjects to long-term $PM_{2.5}$ concentrations above 12 $\mu g/m^3$, removed those data from the analysis, and reran the analysis. Additionally, one commenter provided an explanation of how the restricted analyses were conducted in studies for which he was an author. The commenter notes that for each year a subject was in the study, annual $PM_{2.5}$ concentrations were assigned at the ZIP code level. If they moved, they were assigned the ZIP code level $PM_{2.5}$ concentration for the new ZIP code. The commenter notes that these restricted analyses only included subjects whose annual $PM_{2.5}$ exposure never exceeded that restricted concentration for any year of follow-up in the study. The commenter suggested that the EPA may be concerned as to how $PM_{2.5}$ concentrations in restricted analyses related to a design value since these are exposures for individuals who may have relocated during the study but argue that that is not the point. The commenters assert that while the analyses were restricted to people never exposed above certain concentrations over longer periods of time, the actual $PM_{2.5}$ exposure was one year of exposure in most of these studies. Commenters also suggest that, since the

EPA has deviated from its approach from the 2012 review for considering study-reported mean $PM_{2.5}$ concentrations, the EPA should dismiss its concerns regarding being able to relate the mean $PM_{2.5}$ concentrations from these studies to design values.

First, the EPA agrees with commenters that studies that employ restricted analyses can be used for informing conclusions regarding the appropriate level of the primary annual $PM_{2.5}$ standard. However, the EPA disagrees that the information provided by the commenters provides a sufficient basis for an annual standard level of 8 $\mu g/m^3$. Restricted analyses provide additional support for effects at lower concentrations, exhibiting associations for mean concentrations presumably below the mean concentrations for the main analyses. However, even though commenters note that any individual with exposures over the restricted analyses is excluded from restricted analyses, uncertainties remain with regard to how the mean $PM_{2.5}$ concentrations in restricted analyses compare to design values, particularly in light of the removal of entire ZIP codes from analyses. Design values are calculated based on all measured $PM_{2.5}$ concentrations. When an analysis is restricted below a certain level, some parts of the air quality distribution are removed, but comparing the restricted mean to a design value is not possible because these are two different metrics. For example, in a study that restricts concentrations below 12 $\mu g/m^3$, that represents only part of the air quality distribution, whereas a design value for that study area would include all $PM_{2.5}$ concentrations, not just the ones below 12 $\mu g/m^3$. Therefore, in contrast to means from the main (unrestricted) analysis, it is not possible to compare mean concentrations from restricted analyses to design values. Further, it is unclear how one could evaluate such a relationship between design values and mean $PM_{2.5}$ concentrations from studies that use restricted analyses because the standard is set based on all of its elements (indicator, averaging time, form, and level) and removing $PM_{2.5}$ concentrations from the calculation of the design value for such a comparison would result in a metric that is no longer a design value that would provide the intended protection of the standard. This leads to greater uncertainty in how to use the mean $PM_{2.5}$ concentrations from these studies that use restricted analyses in a similar decision framework as the epidemiologic studies that report long-term mean $PM_{2.5}$ concentrations for health effect associations for the full distribution of $PM_{2.5}$ concentrations.

As described in reaching his conclusions in the section below, the Administrator judges that, despite these uncertainties and limitations, studies that use restricted analyses can provide supplemental information for consideration in reaching conclusions regarding both the adequacy and level of the standard. He notes two studies (Di et al., 2017b and Dominici et al., 2019) are available in this reconsideration that report means in their restricted analyses (restricting annual average $PM_{2.5}$ exposure below 12 $\mu g/m^3$) and used population-weighted approaches to estimate $PM_{2.5}$ exposures and these studies report mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. He recognizes that these studies are just one line of evidence for consideration and that along with the broader evidence base, including the key epidemiologic studies, these studies provide support that the level of the primary annual $PM_{2.5}$ standard should be set below 10 $\mu g/m^3$.

We disagree with the commenters that concerns about relating the mean $PM_{2.5}$ concentrations from restricted analyses to design values are not valid. As an initial matter, restricted analyses were not available and did not inform the 2012 decision to revise the annual $PM_{2.5}$ standard level to 12.0 $\mu g/m^3$. The approach in 2012 in revising the annual standard was to set the level to somewhat below the mean of key epidemiologic studies. As noted above, while the EPA believes that restricted analyses can help inform conclusions regarding the adequacy and the level of the primary annual $PM_{2.5}$ standard, in the context of placing the studies in a decision framework to inform the appropriate level of the annual $PM_{2.5}$ standard, the EPA has not deviated from its approach from the 2012 review. Given that restricted analyses are new since the 2012 review, the EPA disagrees with commenters that uncertainties associated with these studies should not be considered, and that these studies should be used in a similar manner to their main analyses in taking an approach to set a level of the standard somewhat below the lowest long-term reported mean $PM_{2.5}$ concentration. Specifically, as detailed above there are uncertainties and limitations associated with relating the mean $PM_{2.5}$ concentrations from these studies to design values for studies that use restricted analyses, and many of these studies did not expressly report a mean $PM_{2.5}$ concentration for the restricted analysis which makes it impossible to make such a comparison.

Several commenters contend that in considering the accountability studies, the EPA inappropriately reached conclusions regarding the level of the primary annual $PM_{2.5}$ standard based on the starting $PM_{2.5}$ concentrations of these studies, rather than the ending concentrations (*i.e.,* concentrations after a policy was implemented). The commenters assert that these studies provide support for revising the level of the primary annual $PM_{2.5}$ standard to below the proposed range of 9–10 $\mu g/m^3$ to protect public health with an adequate margin of safety.

Accountability studies examine the effect of a policy on reducing $PM_{2.5}$ concentrations in ambient air and evaluate whether such reductions were observed to also lead to reductions in $PM_{2.5}$- associated health outcomes (*e.g.,* mortality). Additionally, accountability studies can reduce uncertainties related to residual confounding of temporal and spatial factors (U.S. EPA, 2022a, p. 3–25). Prior to implementation of the policies, three accountability studies newly available in this reconsideration and assessed in the ISA Supplement, report mean $PM_{2.5}$ concentrations below the level of the current annual standard level (12.0 $\mu g/m^3$) and ranged from 10.0 $\mu g/m^3$ to 11.1 $\mu g/m^3$ (Sanders et al., 2020b; Corrigan et al., 2018; and Henneman et al., 2019). These studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 $\mu g/m^3$, and potentially below the lowest ''starting'' concentrations in these studies of 10.0 $\mu g/m^3$. However, while the small number of studies may provide limited information related to informing the adequacy and level of the annual $PM_{2.5}$ standard, we note that accountability studies are only one line of evidence, and that these studies provide supplemental information for consideration in addition to the full body of evidence. Further, the EPA does not believe it would be appropriate to determine the level of the standard by reference to ending concentrations in accountability studies. Accountability studies are most informative in demonstrating that public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 $\mu g/m^3$, and potentially below the lowest ''starting'' concentrations in these studies of 10.0 $\mu g/m^3$. However, the EPA finds the available information from accountability studies is too limited to support a conclusion that the

appropriate level at which to set the primary annual $PM_{2.5}$ standard would be equal to the ending concentrations of those studies, as the commenters suggest. These studies demonstrate that there are reductions in health outcomes when $PM_{2.5}$ concentrations are reduced in these studies from the starting concentration to the ending concentration, but do not provide support for health effect associations at or below the ending concentrations that would warrant a more stringent standard.

Commenters disagree with the Administrator placing less weight on the epidemiologic studies conducted in Canada when reaching conclusions regarding the level of the primary annual $PM_{2.5}$ standard. These commenters argue that the Canadian epidemiologic studies provide support for setting the level at the lowest end of the proposed range (*i.e.,* 8 μg/m^3) because they report mean $PM_{2.5}$ concentrations, in some cases, below 8 μg/m^3. Commenters disagree with the EPA's reasoning for placing less weight on the Canadian epidemiologic studies, suggesting it conflicts with the approaches in previous PM NAAQS reviews and arguing that the findings of the Canadian epidemiologic studies can be directly translated into a primary annual $PM_{2.5}$ standard. Additionally, while the commenters disagree with the EPA's approach for considering the study-reported mean $PM_{2.5}$ concentrations and design values in general, they note that the CASAC, in their review of the 2021 PA, noted that ''while there may be no design value in Canada, there are data that indicate what a U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S.'' (Sheppard, 2022a, p. 13 of consensus responses). The commenters contend that the EPA failed to acknowledge this advice from the CASAC, specifically noting that the majority of the CASAC highlighted Canadian epidemiologic studies as a part of their rationale for revising the level of the primary annual $PM_{2.5}$ standard to within the range of 8–10 μg/m^3.

In considering the information from the epidemiologic studies in reaching his conclusions, the Administrator considered the full body of evidence, including studies conducted in the U.S. and Canada. However, as described in the proposal and in section II.B.4 below, the Administrator also recognizes that the exposure environments in the U.S. are different from those in Canada. In particular, the U.S. population density is approximately 43 people per square kilometer in the contiguous U.S.[98] compared to Canada, which has one of the lowest population densities on the Earth with 4.2 people per square kilometer (Statistics Canada, 2023). This difference in population density between the U.S. and Canada was not as apparent, and did not need to be highlighted, in the 2012 review given that the available Canadian epidemiologic studies used population-weighting and focused on urban areas where monitors were available and population densities were more comparable with those in the U.S. Given this, the study-reported mean concentrations from U.S. and Canadian studies in the 2012 review were very similar. The recent epidemiologic evidence available in this reconsideration, however, includes studies that utilize approaches that highlight the importance of considering the differences between the two exposure environments in the U.S. versus Canada. When focusing on the recently available Canadian monitor-based epidemiologic studies in this reconsideration, the information indicates that these studies, unlike the studies available in the 2012 review, do not apply population weighting (*e.g.,* Lavigne et al., 2018; Liu et al., 2019). As noted in responding to other public comments above, the absence of population weighting is an important consideration that limits the utility of these studies in informing the appropriate level of the primary annual $PM_{2.5}$ standard. In addition, there are recently available studies in the 2019 ISA and ISA Supplement that expand the geographical extent of the epidemiologic study areas by estimating exposure concentrations in areas where there are no monitors. To do this, these studies use either a statistical extrapolation of monitored values or use air quality modeling and other forms of data (*e.g.,* hybrid model-based approaches). For these Canadian studies, the EPA notes two important considerations in using the information to directly translate to policy decisions regarding the level of the annual standard in the U.S. The first is that in incorporating a larger portion of Canada into these recent studies, more rural areas are included, and as such, the population densities and exposure environment differences become more important. The second is that in analyses that evaluate and validate hybrid models, there is less certainty in $PM_{2.5}$ exposure estimates in more rural areas, which are further from air quality monitors and where $PM_{2.5}$ concentrations in the ambient air tend to be lower (U.S. EPA, 2022b, pp. 2–51 and 2–63). Additionally, it is unclear what portion of the $PM_{2.5}$ concentrations from rural areas are contributing to the study reported mean. Given this, studies that incorporate more rural areas into the epidemiologic studies highlight the importance of considering the differences between the population exposures in the studies themselves and in the U.S. versus Canadian study areas, as well as the influence these differences have on the interpretation of the epidemiologic study results. For these reasons, while the Canadian epidemiologic studies provide additional support for associations between $PM_{2.5}$ concentrations and health effects, the long-term means from Canadian epidemiologic studies are a less certain basis for informing the EPA's selection of the annual standard level, given that it is a U.S.-based standard.

With respect to the CASAC's advice in their review of the 2021 draft PA, the EPA recognizes that the majority of the CASAC pointed to the Canadian studies as supporting their recommendation to revise the annual standard level to within the range of 8–10 μg/m^3. However, the EPA also notes that the CASAC did not advise the EPA to revise the annual standard to a level that was below the study-reported means in the key Canadian epidemiologic studies. Indeed, the CASAC noted that some of the Canadian studies showed associations below 8 μg/m^3, but did not recommend that the Administrator consider levels below 8 μg/m^3 for the annual standard. Further, based on the CASAC's advice, the Administrator is not excluding Canadian studies from his consideration in this reconsideration, but he is considering them in light of the limitations and challenges presented and in the context of the full body of available scientific evidence.

Lastly, the EPA disagrees with commenters that the findings of the Canadian epidemiologic studies can be directly translated into a primary annual $PM_{2.5}$ standard based on the evaluation of the relationship between U.S. study-reported mean $PM_{2.5}$ concentrations and U.S. design values. It is unclear whether the relationship between U.S. study-reported mean $PM_{2.5}$ concentrations and U.S. design values (which, in the case of U.S. hybrid model-based studies, indicates that design values are 15–18% greater than area mean $PM_{2.5}$ concentrations) would apply to the Canadian epidemiologic studies and their reported mean $PM_{2.5}$

[98] All of the key U.S. epidemiologic studies considered in this reconsideration focus on all or subsections of the continental U.S.

concentrations, given that these studies generally report lower $PM_{2.5}$ concentrations than the U.S.-based studies. As such, interpreting the study-reported mean concentrations from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing decisions regarding potential alternative levels of the annual standard, particularly noting the different in exposure relationships in the U.S. versus Canada given the large difference in population densities between the two countries. Further, as mentioned above, while the CASAC advised the EPA to consider the Canadian studies as relevant evidence and found that placing weight on the Canadian studies supported their recommendation to revise the annual standard level to within the range of 8–10 μg/m³, the lower end of their recommended range for the level of the annual standard did not extend below the lower study-reported means from those studies.

Commenters who supported retaining and revising the primary annual $PM_{2.5}$ standard both raised concerns regarding how the EPA used the scientific evidence and quantitative risk assessment related to disparities in $PM_{2.5}$ exposure and risk in informing conclusions on the standard. Commenters who supported retaining the standard assert that the available scientific evidence that demonstrates disparities for minority populations do not support revising the standard, noting that these studies are in areas that tend to have large minority populations and more sources of PM. These commenters contend that because the studies conclude that minority populations experience more effects than others living in the same area that something other than $PM_{2.5}$ concentrations in ambient air is causing the disproportionate impact on minority populations, providing proximity to a source as an example. The commenters note that it is unclear how a national standard will reduce exposure disparities for population groups living in the same area, and further assert that studies of exposure disparities among minority populations were considered in reaching the 2020 final decision to retain the standards.

Conversely, commenters who support revising the standard assert that the at-risk analyses conducted in the 2022 PA provide support for revising the primary annual $PM_{2.5}$ standard to a level of 8 μg/m³. In particular, these commenters state that the at-risk analysis demonstrated that while disparities in mortality risk remain at a standard level of 9.0 μg/m³, disparities in exposure are significantly reduced for an alternative standard level of 8.0 μg/m³ (U.S. EPA, 2022b, p. 3–162).

As discussed in section I above, the primary (health-based) NAAQS are established at a level that is requisite to protect public health, including the health of sensitive or at-risk groups, with an adequate margin of safety.[99] In so doing, decisions on the NAAQS are based on an explicit and comprehensive assessment of the current scientific evidence and associated risk analyses. More specifically, the EPA expressly considers the available information regarding health effects among at-risk populations in decisions on the primary NAAQS. Where populations with disparities in exposure and risk are among the at-risk populations, the decision on the standards is based on providing requisite protection for these and other at-risk populations and lifestages.

The Administrator expressly considered the available information regarding health effects among at-risk populations in reaching the proposed decisions that the current primary annual $PM_{2.5}$ standard is not requisite to protect public health with an adequate margin of safety, and should be revised. The 2019 ISA and ISA Supplement identified children, older adults, people with pre-existing diseases (cardiovascular disease and respiratory disease), minority populations, and low SES populations as at-risk populations. The Administrator is thus, in his final decision, establishing primary $PM_{2.5}$ standards which, in his judgment, will provide protection for these at-risk populations, including minority populations, with an adequate margin of safety.

With respect to the risk assessment, while the EPA notes that the analyses support the conclusion that the primary $PM_{2.5}$ standards are not adequate, as detailed further in the proposal and above in section II.A.3, the EPA also cautions against an over-interpretation of the absolute results. The quantitative risk assessment provides estimates of $PM_{2.5}$-attributable mortality based on input data that include C–R functions from epidemiologic studies that do not quantitatively account for uncertainties in associations between $PM_{2.5}$ exposure and health effects at lower concentrations and are based on an air quality adjustment approach that incorporates proportional decreases in $PM_{2.5}$ concentrations to meet lower alternative standard levels. As a result, simulated air quality improvements used in the risk assessment will always lead to proportional decreases in risk (*i.e.,* each additional μg/m³ reduction produces additional benefits with no clear stopping point), without considering the substantially greater uncertainties associated with the relationship between $PM_{2.5}$ exposures and health effects at lower concentrations.

The same is true for the new at-risk analysis in the risk assessment presented in the 2022 PA that is based on a recent epidemiologic study that is available in this reconsideration that provides mortality risk coefficients for older adults (*i.e.,* 65 years and older) based on $PM_{2.5}$ exposure and stratified by racial and ethnic demographics. Generally, the results of at-risk analyses can vary greatly depending on the inputs to the analyses, including the representativeness of the populations and demographics captured by the study areas that are a part of the analyses, as well as the available C–R functions from epidemiologic studies that stratify by race and ethnicity and the air quality adjustment approaches that are used to simulate air quality at different standard levels. In fact, for this at-risk analysis, the results are even more uncertain than similar estimates from the overall risk assessment due to additional sources of uncertainty specific to the at-risk analysis, such as using C–R functions derived from smaller epidemiologic sample sizes along with the sources of uncertainty that apply to the overall risk assessment (U.S. EPA, 2022b, section 3.4.1.8). Additionally, in characterizing at-risk populations, the at-risk analysis only used one of the air quality adjustment approaches used in the overall risk assessment, which decreases the potential representativeness of the $PM_{2.5}$ concentrations across the study areas (U.S. EPA, 2022b, section 3.4.1.8). Lastly, this at-risk analysis relies on the stratified risk coefficients from only one epidemiologic study.[100] For these reasons, the Administrator places little

[99] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970); see also, *e.g.,* Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998) (''If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard'').

[100] Additional information on all available at-risk epidemiologic studies in this reconsideration are available in section 3.4 and Appendix C of the 2022 PA (U.S. EPA, 2022b, section 3.4, Figure 3–17, and Appendix C, section C.3.2).

weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

While there are substantial uncertainties in the absolute results of the quantitative risk assessment, the EPA also notes that recent scientific evidence evaluated in the ISA Supplement, which built upon the 2019 PM ISA conclusions, found that the evidence ''[c]ontinue[s] to support disparities in $PM_{2.5}$ exposure and health risks by race and ethnicity'' while studies of SES ''provide additional support indicating there may be disparities in $PM_{2.5}$ exposure and health risk by SES'' (U.S. EPA, 2022a, p. 5–4). Thus, in light of the statutory requirement to provide protection for at-risk populations, it is not surprising that the stratified population results of the risk assessment suggest that meeting a revised standard would result in higher risk reductions for minority and low SES populations.

In conclusion, the EPA recognizes that the at-risk analysis was based on one epidemiologic study that stratified by race/ethnicity for older adults (*e.g.,* 65+ years old) and that there is increasing uncertainty in quantitative estimates of stratified risk estimates at the lower end of the range of standard levels assessed. Moreover, the EPA finds that the goal of the NAAQS is to provide the requisite protection to at-risk groups, and where minority populations are included among the at-risk groups, providing requisite protection to minority populations will also result in protecting the public health of other populations. Thus, in setting the NAAQS to protect the health of at-risk groups with an adequate margin of safety, the Administrator is selecting the standard that will provide requisite protection, including for minority populations and other at-risk populations, which also generally results in protecting the public health of other populations and reducing risk disparities.

A number of commenters, primarily from industries and industry groups and some States, support the EPA's proposed decision to retain the primary 24-hour $PM_{2.5}$ standard. Many of these commenters contend that the available scientific evidence and quantitative information has not significantly changed since the 2020 final decision and note that important uncertainties remain. The commenters agree with the EPA's conclusions regarding the controlled human exposure studies and their relationship to short-term peak $PM_{2.5}$ concentrations in ambient air. These commenters also noted the primary annual and 24-hour $PM_{2.5}$ standards work together to provide public health protection, with the 98th percentile form of the 24-hour standard effectively limiting peak daily concentrations. The commenters agree with the EPA that the current suite of standards maintain subdaily concentrations below the higher concentrations in controlled human exposure studies where more consistent health effects are observed. Commenters also agree with the EPA's conclusions that the epidemiologic studies are not useful for informing decisions on the level of the primary 24-hour $PM_{2.5}$ standard because the standard focuses on reducing peak exposures with its 98th percentile form, while the epidemiologic studies often focus on the mean or median as the percentile for which associations with short-term exposures are observed. These commenters also agree with the EPA's focus on U.S.-based studies because of differences compared to Canadian studies. The commenters also generally agree with the Administrator's judgment that it was appropriate to place less weight on the risk assessment, noting that the annual standard is controlling in most areas of the country and revising the annual standard would have the most potential to reduce risk related to $PM_{2.5}$ exposures and would reduce both average (annual) and peak (daily) $PM_{2.5}$ concentrations. Finally, these commenters note that the CASAC did not reach consensus on whether the current primary 24-hour $PM_{2.5}$ standard should be revised, and they agree with the minority of the CASAC's recommendation in their review of the 2021 draft PA that the primary 24-hour primary $PM_{2.5}$ standard should be retained. These commenters also note the CASAC's support in their review of the 2019 draft PA for retaining the primary 24-hour $PM_{2.5}$ standard.

A number of commenters, primarily from public health and environmental organizations and some States, oppose the EPA's proposed decision to retain the primary 24-hour $PM_{2.5}$ standard. These commenters support revising the level of the primary 24-hour $PM_{2.5}$ standard, contending that a more stringent standard is necessary to provide requisite public health protection with an adequate margin of safety, particularly for at-risk groups. In so doing, these commenters place weight on the same aspects of the available scientific evidence as the majority of the CASAC in their review of the 2021 draft PA, and generally advocate for revising the level of the standard to within the range of 25–30 $\mu g/m^3$ as recommended by the majority of the CASAC. Some of these commenters support a level no higher than 25 $\mu g/m^3$ and others support a level of 20 $\mu g/m^3$. These commenters generally cite to the available scientific evidence, including evidence of disproportionate exposures and risks for certain at-risk groups, and the CASAC's advice in support for their recommendation. Some of these commenters also suggest that decisions regarding the primary 24-hour $PM_{2.5}$ standard should not be related to decisions on the primary annual $PM_{2.5}$ standard.

As an initial matter, the EPA disagrees with commenters who suggest that decisions regarding the primary 24-hour $PM_{2.5}$ standard should not be related to decisions on the primary annual $PM_{2.5}$ standard. In reviewing the adequacy of the public health protection afforded by the primary $PM_{2.5}$ standards, the Administrator's consistent past practice has been to evaluate the combination of the annual and 24-hour standards together. In 2012, the then-Administrator concluded that the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures was to set a generally controlling annual standard, and to provide supplemental protection by means of a 24-hour standard set at the appropriate level. In so doing, the then-Administrator explicitly recognized that potential air quality changes associated with meeting a revised annual standard (with a level of 12 $\mu g/m^3$) would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures by lowering the overall distribution of air quality concentrations, and that retaining a 24-hour standard at the appropriate level would ensure an adequate margin of safety against short-term effects in areas with high peak-to-mean ratios (78 FR 3163, January 15, 2013). In this reconsideration, also, the Administrator considers it appropriate to rely on the annual standard (arithmetic mean, averaged over three years) for targeting protection against both long- and short-term $PM_{2.5}$ exposures, noting that the annual standard is typically controlling, while the 24-hour standard (98th percentile, averaged over three years) can provide supplemental protection against the occurrence of peak 24-hour $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.6.3). Further, the Administrator notes that, as in the 2012 review, changes in $PM_{2.5}$ air quality to meet a revised annual standard would

affect the entire distribution of long- and short-term concentrations, thus likely resulting not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations.[101] Thus, the Administrator continues to conclude it is appropriate to consider whether the annual and 24-hour standards together provide requisite protection of public health, rather than considering each standard in isolation.

Regarding the appropriate basis for determining the level of the 24-hour standard, a number of commenters who support revising the primary 24-hour $PM_{2.5}$ standard to a lower level contend that the EPA should not rely on the controlled human exposure studies in evaluating the adequacy of the public health protection afforded by the primary 24-hour $PM_{2.5}$ standard. These commenters support this view by citing the CASAC comments in their review of the 2019 draft PA which advised that controlled human exposure studies have limitations that may impact their ability to inform conclusions on the adequacy of the public health protection afforded by the primary 24-hour $PM_{2.5}$ standard. Commenters noted that these studies do not include the most vulnerable populations and often involve exposure to only one pollutant to elicit a response, and therefore are not representative of real-world exposures.

Other commenters support the EPA's use of the controlled human exposure studies to inform the adequacy of the public health protection and note that the 24-hour standard must at least provide protection against the health effects observed in controlled human exposure studies. Some of the commenters cite the Wyatt et al. (2020) study that demonstrated cardiovascular effects following 2-hour exposures to 120 $\mu g/m^3$ and 4-hour exposures to 37.8 $\mu g/m^3$. Some of these commenters contend that the current primary 24-hour $PM_{2.5}$ standard allows $PM_{2.5}$ exposures comparable to those observed to elicit effects in the controlled human exposure studies, and therefore, the EPA must revise the level of the current standard to protect public health. To support this view, some commenters submitted an analysis of monitoring data from 2017–2020, which compares the number of days per year where maximum daily $PM_{2.5}$ concentrations exceed 120 $\mu g/m^3$ and 37.8 $\mu g/m^3$.

Additionally, other commenters assert that the EPA should focus less on peak $PM_{2.5}$ concentrations ''typically measured'' in areas meeting the current primary $PM_{2.5}$ standards even if they do not exceed the concentrations in the controlled human exposure studies because, in their view, the standard needs to protect against atypical exposures to atypical peak $PM_{2.5}$ concentrations. These commenters conclude that, when considered together, the controlled human exposure studies and the epidemiologic studies warrant strengthening the level of the primary 24-hour $PM_{2.5}$ standard.

The EPA generally disagrees with commenters who contend that it is inappropriate to rely on the controlled human exposures studies in evaluating the adequacy of the public health protection afforded by the primary 24-hour $PM_{2.5}$ standard. The Agency considers these studies informative both for establishing biological plausibility and for determining an appropriate level for the 24-hour standard. When looking to the experimental studies, the EPA finds that the 2019 ISA and ISA Supplement included controlled human exposure studies that report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (and at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). As noted in the 2019 ISA, these studies are important in establishing biological plausibility for $PM_{2.5}$ exposures causing more serious health effects, such as those seen in short-term exposure epidemiologic studies, and they provide support that more adverse effects may be experienced following longer exposure durations and/or exposure to higher concentrations. Additionally, one controlled human exposure study assessed in the ISA Supplement reports evidence of some effects for cardiovascular markers at lower $PM_{2.5}$ concentrations, 4-hour exposures to 37.8 $\mu g/m^3$ (Wyatt et al., 2020). However, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA. The EPA notes that although the controlled human exposure studies do not provide a threshold below which no effects occur, the observed effects in these controlled human exposures studies are ones that signal an intermediate effect in the body, likely due to short-term exposure to $PM_{2.5}$, and typically would not, by themselves, be judged as adverse (88 FR 5620, January 27, 2023) [102] [103]

The EPA notes that the majority of the CASAC, in their review of the 2021 draft PA, commented that these controlled human exposure studies generally do not include populations with substantially increased risk from exposure to $PM_{2.5}$, such as children, older adults, or those with more severe underlying illness, and often involve exposure to only one pollutant to elicit a response. However, both the majority and the minority of the CASAC explained that, even taking into consideration their limitations, the controlled human exposure studies provide some support for assessing the adequacy of the 24-hour standard.[104]

The EPA agrees with the CASAC that the controlled human exposure studies generally do not include populations with substantially increased risk from exposure to $PM_{2.5}$, like children, older adults, or those with pre-existing severe illness, like cardiovascular effects. As such, and as an initial note, these

[101] Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations. However, as noted in 2012, an approach that relied on setting the level of the 24-hour standard such that the 24-hour standard was generally controlling would be less effective and result in less uniform protection across the U.S. than an approach that focuses on setting a generally controlling annual standard (78 FR 3163, January 15, 2013).

[102] Judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), which cooperatively updated the ATS 2000 statement *What Constitutes an Adverse Health Effect of Air Pollution* (ATS, 2000) with new scientific findings, including the evidence related to air pollution and the cardiovascular system (Thurston et al., 2017).

[103] The ATS/ERS described its 2017 statement as one ''intended to provide guidance to policymakers, clinicians and public health professionals, as well as others who interpret the scientific evidence on the health effects of air pollution for risk management purposes'' and further notes that ''considerations as to what constitutes an adverse health effect, in order to provide guidance to researchers and policymakers when new health effects markers or health outcome associations might be reported in future.'' The most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer ''strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,'' providing a general framework for interpreting evidence that proposes a ''set of considerations that can be applied in forming judgments'' for this context (Thurston et al., 2017).

[104] In their review of the 2021 draft PA, the majority of the CASAC advised that ''evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiologic evidence for lowering the standard'' (Sheppard, 2022a, p. 4 of consensus letter). The minority of the CASAC also advised that it was appropriate to place ''more emphasis on the controlled human exposure studies, showing effects at $PM_{2.5}$ concentrations well above those typically measured in areas meeting the current standards'' (Sheppard, 2022a, p. 4 of consensus letter), in evaluating adequacy of the 24-hour standard.

studies are therefore somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations. In spite of this limitation, the EPA also agrees with the CASAC, that even taking into consideration the limitations of the controlled human exposure studies, these studies can provide some support for evaluating the adequacy of the 24-hour standard. However, the EPA further notes that while the controlled human exposure studies are important in establishing biological plausibility, the health outcomes observed in these controlled human exposure studies are often ''intermediate'' outcomes (*i.e.,* not always clearly adverse) and therefore it is unclear how the importance of the effects observed in the studies should be interpreted with respect to adversity to public health. The EPA finds that it is appropriate to consider these study limitations in assessing the information provided by controlled human exposure studies in evaluating the adequacy of the primary 24-hour $PM_{2.5}$ standard.

The EPA agrees with commenters that the primary 24-hour $PM_{2.5}$ standard must at least provide protection against the health effects consistently observed in controlled human exposure studies. As discussed in the proposal, the EPA looks at whether the exposures that elicit a response following exposure to $PM_{2.5}$ in the controlled human exposure studies occur under recent air quality conditions in areas meeting the current standards. Based on these air quality analyses, the EPA concludes that these types of exposures very rarely occur when the current standards are being met.

The EPA did receive multiple comments questioning these results and the approach in the EPA's analyses. For example, some commenters submitted an analysis of monitoring data from 2017–2020, which compares the number of days per year where maximum daily $PM_{2.5}$ concentrations exceed 120 $\mu g/m^3$ and 37.8 $\mu g/m^3$ and evaluate the number of days subset by groups of monitors with 4-year average $PM_{2.5}$ concentrations close to the levels of combinations of current and proposed annual (+/− 0.2 $\mu g/m^3$) and 24-hour (+/−2 $\mu g/m^3$) $PM_{2.5}$ standards. To support their view that the primary $PM_{2.5}$ standards should be revised, the commenters describe decreases in days per monitor per year with 2-hour maximum concentrations greater than 120 $\mu g/m^3$ and 4-hour maximum concentrations greater than 37.8 $\mu g/m^3$ when comparing monitors that achieve close to 10 and 30 $\mu g/m^3$ versus monitors that meet close to 8 $\mu g/m^3$ and 25 $\mu g/m^3$. The commenters noted decreases in the number of days per monitor per year with 2-hour maximum concentrations over 120 $\mu g/m^3$ and 4-hour max concentration over 37.8 $\mu g/m^3$ were also seen when comparing monitors close to achieving 24-hour standards with levels of 35 $\mu g/m^3$ versus 25 $\mu g/m^3$.

First, the EPA notes that this analysis submitted by commenters was limited to a very small number of monitors and did not include a national perspective. Second, the EPA notes that this analysis focused on number of days (rather than the number of times) where there was a 2-hour maximum concentration over 120 $\mu g/m^3$ or a 4-hour max concentration over 37.8 $\mu g/m^3$. In order to evaluate the protection provided by the current 24-hour standard against peak exposures, including exposures with 2-hour concentrations greater than 120 $\mu g/m^3$ and 4-hour concentrations greater than 37.8 $\mu g/m^3$, the EPA considers it more informative and appropriate from a public health perspective to assess the number of times a subdaily exposure of concern occurs in a year, rather than the number of days on which they occur because the former identifies more potential exposures of concern and provides more information about the scale and scope of the occurrences of those exposures. Lastly, the analyses allowed monitors somewhat above the standards to be included. Therefore, it is unclear whether the exceedances of the 2-hour or 4-hour benchmarks would still have occurred if the area had actually been meeting the current primary $PM_{2.5}$ standards. However, in considering the analyses submitted by the commenters, the EPA conducted new analyses [105] that looked at all individual monitors across the U.S. and evaluated the percentage of times the monitors experienced a 2-hour maximum concentration over 120 $\mu g/m^3$ or a 4-hour max concentration over 37.8 $\mu g/m^3$ when that monitor was meeting the current standards. Further, given that the Administrator concludes that the level of the current primary annual $PM_{2.5}$ is not adequate and that it should be revised to 9.0 $\mu g/m^3$, the new analysis evaluates the percentage of times during a recent 3-year period (*i.e.* 2019–2021) that individual monitors experienced a 2-hour maximum concentration over 120 $\mu g/m^3$ or a 4-hour max concentration over 37.8 $\mu g/m^3$ when that monitor was meeting the current primary 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$ and a revised primary annual $PM_{2.5}$ standard of 9.0 $\mu g/m^3$.

In evaluating the results from the new analyses, it is important to keep in mind that the 2019 ISA and ISA Supplement concluded that the most consistent evidence from the controlled human exposures studies is for impaired vascular function following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 $\mu g/m^3$, with less consistent evidence for effects following exposures to concentrations lower than 120 $\mu g/m^3$. The new analyses show that across all monitors, on average, only 0.029 percent of 2-hour observations reach $PM_{2.5}$ concentrations higher than 120 $\mu g/m^3$ in areas meeting the current 24-hour standard and a revised annual standard of 9.0 $\mu g/m^3$. Further, recognizing that one purpose of the 24-hour standard is to protect against exposure in areas with high peak-to-mean ratios, when assessing the monitors individually across the U.S. under these same conditions, the monitors reporting the highest $PM_{2.5}$ concentrations have only 0.47 percent of 2-hour observations reach $PM_{2.5}$ concentrations higher than 120 $\mu g/m^3$.

Additionally, the analyses also evaluated the frequency of reporting a 4-hour maximum concentration over 37.8 $\mu g/m^3$ when monitors were meeting the current 24-hour standard and a revised annual standard of 9.0 $\mu g/m^3$. For this part of the analysis, the EPA finds that across all monitors, on average, only 0.41 percent of 4-hour observations reach $PM_{2.5}$ concentrations higher than 37.8 $\mu g/m^3$ in areas meeting the current 24-hour standard and a revised annual standard of 9.0 $\mu g/m^3$. Further, when assessing the monitors individually across the U.S. under these same conditions, the monitors reporting the highest $PM_{2.5}$ concentrations have only 2.6 percent of 4-hour observations reach $PM_{2.5}$ concentrations higher than 37.8 $\mu g/m^3$. Thus, the EPA disagrees with commenters that the current primary 24-hour $PM_{2.5}$ standard typically allows $PM_{2.5}$ exposures at or above those observed to cause health effects in controlled human exposure studies. Furthermore, the EPA notes that in light of the small number of occurrences and the intermediate nature of the effects observed in Wyatt et al. (2020) at concentrations of 37.8 $\mu g/m^3$ (*i.e.,* effects that typically would not, by themselves, be judged as adverse), there is substantial basis to doubt whether further improvements in public health

[105] Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

would be achieved by further reducing these exposures. In drawing this conclusion, the EPA notes the lack of evidence of effects from controlled human exposure studies at levels below the current 24-hour standard and the fact that the results of Wyatt et al. (2020) are inconsistent with other currently available studies, and this study only observes intermediate effects.

In response to commenters that cited the majority of the CASAC's view that, in general, ''[t]here is . . . less confidence that the annual standard could adequately protect against health effects of short-term exposures'' (Sheppard, 2022a, p. 4 of consensus letter), the EPA disagrees with the majority of CASAC, noting that the results of the EPA's analysis suggest that high peak concentrations are extremely infrequent in areas meeting an annual standard of 9.0 μg/m^3, occurring less than 0.029–0.41 percent of the time (for 2-hour concentrations >120 μg/m^3 and 4-hour concentrations >37.8 μg/m^3, respectively). This suggests that in most locations, even the upper tail of the distribution would be controlled quite well under a revised annual standard. With regard to the likelihood that the current standards would allow peak concentrations that are clearly of concern from a health perspective, therefore, the EPA concludes that such occurrences are extremely infrequent—and will be even less frequent under the improved air quality conditions associated with meeting a revised annual $PM_{2.5}$ standard of 9.0 μg/m^3.

A number of commenters who support revising the primary 24-hour $PM_{2.5}$ standard to a lower level suggest that the available epidemiologic evidence provides support for such a revision. To support their view, the commenters note that the currently available evidence, including a number of epidemiologic studies that demonstrate associations between short-term $PM_{2.5}$ exposures and health effects, provides support for causal relationships for short-term $PM_{2.5}$ exposures and health effects as described in the 2019 ISA and ISA Supplement. The commenters further note that the available epidemiologic studies include diverse populations that are broadly representative of the U.S. population, including at-risk populations, which they assert is an advantage over the controlled human exposure studies and the risk assessment, which are not as broadly representative.

These commenters highlight a number of specific epidemiologic studies that they suggest provide support for revising the level of the 24-hour standard. Additionally, commenters contend that there are epidemiologic studies using restricted analyses that show that positive and statistically significant associations between short-term $PM_{2.5}$ exposure and mortality persist at daily mean concentrations below 25 μg/m^3. The commenters also cite several studies that provide no evidence of a threshold. These commenters also point to the CASAC advice in their review of the 2021 draft PA, where the majority of the CASAC cited epidemiologic studies using restricted analyses as offering support for revision. The commenters argue that the EPA cannot base discretion on uncertainties related to the methods used in restricted analyses in the epidemiologic studies. In so doing, these commenters disagree with the EPA that it is important to take into consideration that these studies do not consider the form or averaging time of the 24-hour standard. Finally, the commenters claim that while the EPA stated that the study-reported means from epidemiologic studies that use restricted analyses are more useful for identifying impacts from typical 24-hour exposures than for peak 24-hour exposures, the commenters assert that the studies also indicate that there are health risks at relatively high concentrations below the current level of the primary 24-hour $PM_{2.5}$ standard that must be addressed.

As noted by the commenters, epidemiologic studies that show positive and statistically significant associations between short-term $PM_{2.5}$ exposure and mortality provide support for the causal determination in the 2019 ISA. The EPA also agrees that the available epidemiologic studies include diverse populations that are broadly representative of the U.S. population, including at-risk populations. Further, the EPA agrees that studies evaluated in the 2019 ISA and the ISA Supplement continue to provide evidence of linear, no-threshold concentration-response relationships, but with less certainty in the shape of the curve at lower concentrations (*i.e.,* below about 8 μg/m^3), with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2).

However, findings of positive, significant associations in short-term epidemiologic studies do not directly indicate that short-term effects would occur in areas meeting the 24-hour standard and therefore, do not directly address the question of whether the current 24-hour standard is adequate. While short-term epidemiologic studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, they do not identify the specific exposures (*i.e.,* a specific 24-hour concentration) that can lead to the reported effects. Short-term epidemiologic studies evaluate the association between day-to-day variation in daily (24-hour) $PM_{2.5}$ exposure and health endpoints (*e.g.,* mortality) to understand how these changes in air pollution concentrations are associated with changes in health outcomes. But these studies do not report daily concentrations; rather, they report the long-term mean concentration of the 24-hour $PM_{2.5}$ concentrations over the entire multi-year period of the study, and typically report their results as a relative risk (*e.g.,* for each 10 μg/m^3 increase in $PM_{2.5}$, the risk of mortality or cardiovascular hospital admissions increases by a certain percentage, across the full range of the 24-hour $PM_{2.5}$ concentrations in the study). This means that there is no specific point in the air quality distribution of any epidemiologic study that represents a ''bright line'' at and above which effects have been observed and below which effects have not been observed. Nor, as noted above, do these studies allow for any direct inferences about health impacts associated with the short-term ''peak'' exposures that the primary 24-hour standard is designed to protect against. While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures in these epidemiologic studies reflect days with ambient $PM_{2.5}$ concentrations around the mean or middle of the air quality distributions examined (*i.e.,* ''typical'' days rather than days with extremely high or extremely low concentrations). This is true of long-term epidemiologic studies as well. The difference between epidemiologic studies examining associations with long-term exposures and short-term exposures is comparing different levels of exposure over different exposure durations (*i.e.,* long-term studies exposures are defined as those that are annual or multi-year, while short-term exposures are defined as those that are mostly 24-hour) (U.S. EPA, 2019a, section P.3.1). Thus, in both cases, and in the absence of a discernible threshold, epidemiologic studies of short-term and long-term exposures provide the strongest support and confidence for reported health effect associations around the middle portion of the $PM_{2.5}$ air quality distribution (*e.g.,* the study-reported mean $PM_{2.5}$

concentration), which corresponds to the bulk of the underlying data, rather than at the extreme upper or lower ends of the distribution. However, the difference between the annual standard and the 24-hour standard, aside from averaging times, is that the form of the annual standard is a mean $PM_{2.5}$ concentration, which is based on the bulk of the air quality data, while the form of the 24-hour standard is a 98th percentile form, which is based on peak concentrations. Both long-term and short-term epidemiologic studies are informative for determining the appropriate level of the annual $PM_{2.5}$ standard, which is designed to control ''typical'' daily exposures and risks, because these studies most often report long-term mean (or median) $PM_{2.5}$ concentrations that are representative of ''typical'' exposures that are associated with health effects. In contrast, while the short-term epidemiologic studies examine health effects associated with shorter exposure durations (*e.g.,* mostly 24-hour exposures), these studies are less informative for determining the appropriate level of the 24-hour $PM_{2.5}$ standard because these studies do not report the 98th percentile $PM_{2.5}$ concentrations,[106] which is more directly comparable to the form of the 24-hour standard. Additionally, if the 98th percentile of data were reported, the EPA would consider the peak concentrations observed in these studies (which by definition rarely occur) in conjunction with other supporting evidence. However, as already noted, there is an absence of new information in this reconsideration (either from controlled human exposure studies or epidemiologic studies) suggesting that peak concentrations just below the level of the current 24-hour standard (with its level of 35 $\mu g/m^3$) are associated with adverse effects. Instead, the evidence links risk to more typical daily exposures near the middle of the air quality distribution—exposures most effectively controlled through a strengthening of the annual standard. As noted in the 2012 final rule, ''reducing the annual standard is the most efficient way to reduce the risks from short-term exposures . . . as the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations'' (78 FR 3156, January 15, 2013).

As noted above, in evaluating the adequacy of the current standards, the EPA has consistently considered the annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98th percentile concentrations) together in evaluating the public health protection provided by the standards against the full distribution of short- and long-term $PM_{2.5}$ exposures. Moreover, the EPA has previously noted that the annual standard is generally controlling in most parts of the country, providing an effective and efficient way to reduce total population risk to both long- and short-term $PM_{2.5}$ exposures, while the 24-hour standard, with its 98th percentile form, provides supplemental protection, particularly for areas with high peak-to-mean ratios of 24-hour $PM_{2.5}$ concentrations (78 FR 3158, January 15, 2013). In such areas, annual average $PM_{2.5}$ concentrations could be quite low, and the 24-hour standard provides a means of ensuring control of episodic peaks possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The approach taken in evaluating the adequacy and alternative levels of the annual standard has been to evaluate the long-term mean $PM_{2.5}$ concentrations of both long-term and short-term key epidemiologic studies, where we have the most confidence in the reported health effects association, while also giving some consideration to lower percentiles of the air quality distribution (*e.g.,* 25th percentiles). However, using a similar approach to evaluate the adequacy of the current and any potential alternative levels of the 24-hour standard with short-term epidemiologic studies, as the majority of CASAC and some commenters are suggesting, presents challenges.

Short-term epidemiologic studies, including those that use restricted analyses, often report metrics that include mean $PM_{2.5}$ concentrations, with some studies also reporting lower percentiles, such as the 25th percentile. As previously noted above, for studies of daily $PM_{2.5}$ exposure, which examine associations between day-to-day variation in $PM_{2.5}$ concentrations and health outcomes, often over several years, most of the estimated exposures reflect days with ambient $PM_{2.5}$ concentrations around the middle of the air quality distributions examined (*i.e.,* the mean or median). However, there is not a metric or statistic reported in short-term epidemiologic studies that allows for a direct comparison to the current 24-hour $PM_{2.5}$ standard and its 98th percentile form. While a 98th percentile of $PM_{2.5}$ concentrations is a metric that might be more closely compared to the 24-hour standard level, 98th percentile $PM_{2.5}$ concentrations were not reported in key epidemiologic studies. Consistent with the Administrator's final decision in 2012, the EPA notes that even if 98th percentile values were reported, it would be inappropriate to focus on these concentrations without also considering the impact of a revised annual standard on short-term concentrations, since many areas would be expected to experience decreasing short- and long-term $PM_{2.5}$ concentrations in response to a revised annual standard (78 FR 3156, January 15, 2013). Furthermore, in light of the scarcity of days at the very upper end of the distribution, and to avoid placing undue reliance on the peak concentrations observed in these studies (which by definition rarely occur), the EPA finds that such values would need to be considered in conjunction with other supporting evidence. In addition, as described above, the other lines of evidence available for consideration by the EPA do not indicate that the current primary 24-hour standard requires revision to protect public health with an adequate margin of safety. The EPA notes again the lack of corroborating evidence from controlled human exposure studies. While the EPA agrees with the CASAC that the controlled human exposure studies are limited in their ability to speak to the concentrations at which effects may be elicited in at-risk populations, as discussed above the lowest concentration associated with effects is 37.8 $\mu g/m^3$ and the effects observed were ''intermediate'' outcomes that are not by themselves considered adverse. We also note that, as detailed in section II.A.2.a above, the study that observed intermediate effects at concentrations of 37.8 $\mu g/m^3$ was evaluated in the ISA Supplement and the results of this study were inconsistent with the controlled human exposure studies evaluated in the 2019 ISA. Additionally, as noted above, the EPA finds that across all monitors, on average, only 0.41 percent of 4-hour observations reach $PM_{2.5}$ concentrations higher than 38 $\mu g/m^3$ in areas meeting the current 24-hour

[106] In the 2022 PA, the EPA has identified a number of key areas for additional research and data collection for $PM_{2.5}$, based on the uncertainties and limitations that remain in the scientific evidence and technical information. In addition to research and data collection, the EPA specifically highlights additional information that could be reported in the epidemiologic studies that may help inform future reviews of the primary $PM_{2.5}$ standards, including additional descriptive statistics in the upper percentiles of the air quality distribution (*i.e.,* from the 95th to the 99th percentile), as well as the number of days of concentrations and/or health events within each of these percentiles (U.S. EPA, 2022a, section 3.7).

standard and a revised annual standard of 9.0 μg/m³. Given the rarity of these occurrences and the fact that the effects associated with exposures to this $PM_{2.5}$ concentration have not been found to be adverse in and of themselves, the EPA finds it reasonable to conclude that this pattern of air quality will protect at-risk populations, even though such populations were not in the study groups. The EPA concludes that further evidence would be needed at specific short-term (*i.e.,* hourly or daily) concentrations below the level of the current 24-hour standard to support any revision to the current 24-hour standard.

With regard to the data that are available from the short-term epidemiologic studies (which, as noted, do not include 98th percentile values), the EPA considers it inappropriate to utilize the study-reported means from the short-term epidemiologic evidence to assess the adequacy of the 24-hour standard, with its 98th percentile form, considering that the study-reported mean concentrations do not provide meaningful insight regarding the frequency or health significance of peak concentrations occurring during the study period. As indicated in the 2022 PA, the study-reported means of short-term epidemiologic studies do not serve a purpose in determining a level at which we can confidently attribute effects to the impact of ''peak'' exposures. The 24-hour standard is intended to provide supplemental protection against short-term peak exposures and while there is a general relationship between mean concentrations and 98th percentile concentrations in individual locations, such relationships vary by location and there is not an established relationship that can be relied upon to predict 98th percentile concentrations based on mean $PM_{2.5}$ concentrations reported in multi-city epidemiologic studies. Instead, mean concentrations from short-term epidemiologic studies are more useful in addressing questions regarding the effects of ''typical'' or average 24-hour exposures, which are addressed through the annual standard. For this reason, the EPA does consider the mean concentrations of short-term studies (as well as the means from the long-term studies) in evaluating the level of the annual standard, which the EPA recognizes as the generally controlling standard for both long- and short-term exposures. However, the EPA does not agree with commenters that it is appropriate to use means from short-term epidemiologic studies as the basis for a decision-making framework to determine the adequacy of the current 24-hour standard, with its 98th percentile form.

As described in the proposal (88 FR 5613, January 27, 2023), the 2022 PA also noted the epidemiologic studies that restrict 24-hour average $PM_{2.5}$ concentrations to values of less than 35 μg/m³, and in some cases less than 25 μg/m³, and annual average $PM_{2.5}$ concentrations less than 12 μg/m³. Restricted analyses use a subset of data from their main analyses and conduct an epidemiologic study with health events that occur at concentrations below a certain concentration (*e.g.,* 25 μg/m³). While some of these studies do not report the mean $PM_{2.5}$ concentration for the restricted analysis, the mean of the restricted analysis is presumably less than the mean $PM_{2.5}$ concentration in the main analysis. Restricted analyses from long-term and short-term exposure epidemiologic studies are informative in providing support that the health effects associations are not driven by just the upper peaks of the $PM_{2.5}$ air quality distributions and provide support for revision to the level of the annual $PM_{2.5}$ standard. Short-term restricted analyses also report positive associations between short-term $PM_{2.5}$ exposure and morbidity and mortality. As an example, in a restricted analysis evaluating the association between short-term exposures and $PM_{2.5}$ concentrations less than 25 μg/m³, Di et al. (2017a) removed 6.3 percent of the data from their main analyses, (*i.e.,* all $PM_{2.5}$ concentrations greater than 25 μg/m³), and still found a positive and significant association between short-term $PM_{2.5}$ exposure and mortality. This study provides additional support that the association between short-term exposure to $PM_{2.5}$ and mortality in the main epidemiologic analysis is not driven by the upper peaks of the $PM_{2.5}$ air quality distribution, which in turn supports the conclusion that lowering the entire distribution of air quality concentrations through a revised annual standard is an appropriate means of protecting against adverse effects from short-term exposure, as discussed further below.

In their review of the 2021 draft PA, the majority of the CASAC highlighted three U.S.-based epidemiologic studies that restricted 24-hour average $PM_{2.5}$ concentrations below 25 μg/m³ as a part of their rationale for recommending that the EPA revise the level of the primary 24-hour $PM_{2.5}$ standard. Similarly, in evaluating positive associations in restricted analyses, some commenters also suggest that because an association exists at 24-hour concentrations below 25 μg/m³, the 24-hour standard level should be set at the concentration at which the analysis was restricted (*e.g.,* 25 μg/m³). However, the EPA notes that neither the CASAC nor public commenters provided any detail regarding, how, in their view, these studies demonstrate that the level of the current 24-hour standard is not adequate, and/or how these studies demonstrate what revised level of the 24-hour standard would provide requisite public health protection with an adequate margin of safety. The EPA considers that such an approach would have several important limitations. First, the approach assumes that a specific point on the air quality distribution (*e.g.,* the point at which the analysis was restricted) is where health effects are exhibited and where we have the most confidence in the reported association. However, in addition to the limitations associated with the short-term epidemiologic studies outlined above, the EPA does not agree that it would be appropriate to identify the requisite level of the primary 24-hour $PM_{2.5}$ standard based on the specific concentration at which the analyses restrict their studies. The choice to restrict the data at a particular concentration is in effect arbitrary, and does not establish that any particular effects are attributable to that concentration as opposed to other concentrations within the restricted analysis.

Further, these restricted analyses do not report the $PM_{2.5}$ concentration at the 98th percentile of data or other metrics relating to the upper end of the distribution that could provide information about health risks associated with peak exposures. For example, the CASAC does not provide a discussion of what the comparable 98th percentile concentration is in the distribution of remaining 24-hour $PM_{2.5}$ concentrations of restricted analyses (because such data is not reported by the study authors) and what degree of confidence the Administrator should place on those upper percentile values (*e.g.,* 98th percentile values). In order to identify a level of the 24-hour standard based on associations between the ''upper end'' of exposures, either in the unrestricted or the restricted analyses, and adverse health effects, it would be necessary to have both greater detail on the distribution of air quality in the study and greater confidence in the reported association at the peak concentrations such as the 98th percentile—in other words, a better understanding of how specific 24-hour concentrations correspond to the frequency and total number of observed health events in the study.

Further, the EPA notes that when resulting analyses based on the

restricted dataset continue to find positive associations between the remaining air quality distribution and health effects, it suggests that the relationship was in fact not driven primarily by the upper tail (now removed from the dataset) but rather by lower portions of the distribution of air quality. In other words, we have no confidence that the remaining upper end of the air quality distribution is driving the remaining associations reported in the restricted analyses, as opposed to the vast array of health events at and around the mean $PM_{2.5}$ concentration. In fact, it is reasonable to conclude that to effectively address the health effects observed in the study, it is necessary to control not just the peak concentrations but to reduce the bulk of the exposures (occurring near the mean), a task more effectively achieved, as noted above through a tightening of the annual standard, which has the effect of shifting the entire distribution of $PM_{2.5}$ concentrations downward (both peaks and means). Therefore, while the EPA agrees that both short- and long-term epidemiologic studies that completed restricted analyses and reported the resulting study means could be used to inform conclusions regarding the adequacy of the annual standard, given that the resulting study means (when reported) could be evaluated in the context of the decision framework described above for informing decisions on the level of the annual standard, the EPA considers that current short-term epidemiologic studies that restrict analyses are subject to the same limitations outlined above for current short-term epidemiologic studies in how they can be used in a decision-making framework to inform the adequacy and alternative level of the primary 24-hour $PM_{2.5}$ standard. As such, while the available short-term epidemiologic studies that restrict their analyses are useful for informing conclusions regarding the strength of the associations for health outcomes, they are not, as currently designed, as useful for informing conclusions regarding the adequacy of the current primary 24-hour $PM_{2.5}$ standard. In reaching this conclusion, the EPA notes that the majority of the CASAC did not address the limitations of these studies outlined in the 2021 draft PA, particularly in the context of the 24-hour standard with its 98th percentile form. Among the future research needs identified by the EPA in the 2022 final PA, the Agency noted a number of gaps in the currently available information reported in the epidemiologic studies of short-term exposure, including ''descriptive statistics of $PM_{2.5}$ concentrations at individual percentiles from the 95th percentile to the 99th percentile, as well as the number of days of concentrations and/or health events within each of these percentiles'' and other descriptive statistics and details regarding analytical design in studies employing restricted analyses (U.S. EPA, 2022b, pp. 3–225 to 3–226). Such information could significantly improve the EPA's ability to draw conclusions from these studies with regard to the adequacy of the current primary 24-hour $PM_{2.5}$ standard.

Due to the limitations and uncertainties outlined above, in reaching his decision on the primary 24-hour $PM_{2.5}$ standard, the Administrator judges that the information from currently available short-term epidemiologic studies, including those that use restricted analyses, is inadequate to inform decisions regarding the adequacy of the current 24-hour standard. Additionally, consistent with the final decision in 2012, the EPA continues to view an approach that focuses on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures. Potential air quality changes associated with meeting an annual standard level of 9.0 $\mu g/m^3$ will result in lowering risk associated with both long- and short-term $PM_{2.5}$ exposure by lowering the overall air quality distribution. As discussed above, reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in the epidemiologic studies, as the available evidence suggests the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations. However, as in the 2012 review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term $PM_{2.5}$ exposures in all parts of the country, particularly in areas with high peak-to-mean ratios, and concludes that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard. In so doing, the Administrator concludes that retaining the level of the primary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ will provide requisite protection against short-term peak $PM_{2.5}$ concentrations, in conjunction with a revised annual standard level of 9.0 $\mu g/m^3$.

4. Administrator's Conclusions

This section summarizes the Administrator's considerations and conclusions related to the adequacy of the current primary $PM_{2.5}$ standards and presents his decision to revise the primary annual $PM_{2.5}$ standard to a level of 9.0 $\mu g/m^3$ and retain the primary 24-hour $PM_{2.5}$ standard. In establishing primary standards under the Act that are ''requisite'' to protect public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified. However, the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Given these requirements, the Administrator's final decision in this reconsideration is a public health policy judgment drawing upon scientific and technical information examining the health effects of $PM_{2.5}$ exposures, including how to consider the range and magnitude of uncertainties inherent in that information. This public health policy judgment is based on an interpretation of the scientific and technical information that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn, and is informed by the Administrator's consideration of advice from the CASAC and public comments received on the proposal.

The initial issue to be addressed in the reconsideration of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge and other information reflected in the 2019 ISA, ISA Supplement, and 2022 PA, the current standards are requisite to protect public health with an adequate margin of safety. In considering the adequacy of the current suite of primary $PM_{2.5}$ standards, the Administrator has considered the large body of evidence presented and assessed in the 2019 ISA and ISA Supplement, the conclusions presented in the 2022 PA, the views expressed by the CASAC, and public comments. The Administrator has taken into account both evidence- and risk-based considerations in developing final conclusions on the adequacy of the current primary $PM_{2.5}$ standards. The Administrator has additionally

considered the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the conclusions on the adequacy of the current primary $PM_{2.5}$ standards.

In evaluating the adequacy of the current standards, the Administrator first recognizes the longstanding body of health evidence supporting relationships between $PM_{2.5}$ exposures (short- and long-term) and mortality and serious morbidity effects. The evidence available in this reconsideration (*i.e.,* that assessed in the 2019 ISA and ISA Supplement) and summarized above in section II.A.2.a reaffirms, and in some cases strengthens, the conclusions from the 2009 ISA regarding the health effects of $PM_{2.5}$ exposures. Recent epidemiologic studies demonstrate generally positive and often statistically significant associations between $PM_{2.5}$ exposures and a number of health effects, including non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (*e.g.,* lung cancer mortality or incidence, asthma development). Recent controlled human exposure and animal toxicological studies, as well as evidence from epidemiologic panel studies, strengthens support for potential biological pathways through which $PM_{2.5}$ exposures could lead to the serious effects reported in many population-level epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. In considering the available scientific evidence, and consistent with approaches employed in past NAAQS reviews, the Administrator places the most weight on evidence supporting ''causal'' or ''likely to be causal'' relationship with long or short-term $PM_{2.5}$ exposures. In addition, the Administrator also takes note of those populations identified to be at greater risk of $PM_{2.5}$-related health effects, as characterized in the 2019 ISA and ISA Supplement, and the potential public health implications.

In evaluating what existing or revised standards may be requisite to protect public health, as described above in section II.A.2, the Administrator's approach recognizes that the current annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98th percentile concentrations), together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. This approach recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations.

Further, consistent with the approach adopted in 2012, the Administrator concludes that the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures is to set a generally controlling annual standard, and to provide supplemental protection against the occurrence of peak 24-hour $PM_{2.5}$ concentrations by means of a 24-hour standard set at the appropriate level. In reaching this conclusion, the Administrator explicitly recognizes that air quality changes associated with meeting a revised annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures by lowering the overall distribution of air quality concentrations, leading to not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations. However, as noted in 2012, he also recognizes that an approach that relies on setting the level of the 24-hour standard such that the 24-hour standard is generally controlling would be less effective and result in less uniform protection across the U.S. than an approach that focuses on setting a generally controlling annual standard. Thus, he concludes that relying on a revised annual standard as the controlling standard will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard. He further concludes that retaining a 24-hour standard at the appropriate level will ensure an adequate margin of safety against short-term effects in areas with high peak-to-mean ratios.

In light of his focus on the annual standard as the generally controlling standard, in considering whether the primary $PM_{2.5}$ standards are adequate, the Administrator first considers information available to inform his final conclusions regarding the primary annual $PM_{2.5}$ standard. In so doing, he notes that in this reconsideration, a large number of key U.S. epidemiologic studies report positive and statistically significant associations for air quality distributions with overall mean $PM_{2.5}$ concentrations that are well below the current level of the annual standard of 12.0 $\mu g/m^3$. He further recognizes that there is additional scientific evidence assessed in the 2019 ISA and newly assessed in this reconsideration in the ISA Supplement that can provide supplemental information to inform his decisions. In addition to the key U.S. epidemiologic studies, the Administrator also recognizes that key Canadian epidemiologic studies also demonstrate positive and statistically significant associations at concentrations below 12 $\mu g/m^3$. He also recognizes that epidemiologic studies that restrict annual average $PM_{2.5}$ concentrations to below 12 $\mu g/m^3$ also provide support for positive and statistically significant associations at lower mean $PM_{2.5}$ concentrations, as do accountability studies that also suggest public health improvements may occur at concentrations below 12 $\mu g/m^3$.

With regard to the available scientific evidence to inform his final decisions on the adequacy of the current 24-hour standard, the Administrator finds that there is less information available to support decisions on the 24-hour standard than that summarized above for the annual standard. The Administrator first notes that controlled human exposure studies, including those newly available in this reconsideration, demonstrate effects following short-term $PM_{2.5}$ exposures at concentrations higher than the current 24-hour standard. The Administrator also considers air quality analyses conducted in the 2022 PA and in responding to public comments, as described above in section II.B.3, that evaluate $PM_{2.5}$ concentrations in ambient air for similar durations to the controlled human exposure studies. As noted above, these air quality analyses indicate that the current 24-hour standard, particularly in conjunction with the revised level of the annual standard, provides a high degree of protection against subdaily $PM_{2.5}$ concentrations that have been shown to elicit effects in controlled human exposure studies. The Administrator considers a limited number of available epidemiologic studies that report associations with health effects when the analyses are restricted to daily $PM_{2.5}$ concentrations below 35 $\mu g/m^3$. As described above, although these studies are useful in demonstrating that health effects are associated with exposure to daily $PM_{2.5}$ concentrations in the lower part of the air quality distribution, they do not provide information about health effects associated with the short-term

''peak'' exposures that the 24-hour standard is designed to protect against. Accordingly, these studies have limited relevance in informing a decision about the appropriate level of the 24-hour standard.

In addition to the scientific evidence, the Administrator also considers the information from the risk assessment. In so doing, he notes that the risk assessment estimates that the current primary annual $PM_{2.5}$ standard could allow a substantial number of deaths in the U.S. With respect to the 24-hour standard, the Administrator recognizes that there are only a small number of study areas where the 24-hour standard is controlling and changes in the 24-hour standard level are estimated to have a much smaller impact on public health. The Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, they should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. While the Administrator recognizes that these uncertainties are important, he also notes that the general magnitude of the risk estimates provide support for significant public health impacts, particularly for lower alternative annual standard levels.

In reaching his final conclusions regarding the adequacy of the primary $PM_{2.5}$ standards, the Administrator also considers the CASAC's advice and recommendations, as well as public comments. With respect to the CASAC's advice, the Administrator recognizes that, in their review of the 2021 draft PA, the CASAC reached consensus that the current primary annual $PM_{2.5}$ standard is not adequate and that it is not sufficiently protective of public health. The Administrator also takes note of the CASAC's advice in their review of the 2019 draft PA, where the CASAC did not reach consensus on the adequacy of the primary annual $PM_{2.5}$ standard, with the minority recommending revision and the majority recommending the standard be retained. Furthermore, he recognizes that in reviewing the 2019 draft PA, the CASAC reached consensus regarding the adequacy of the primary 24-hour $PM_{2.5}$ standard, concluding that the standard should be retained. Conversely, in their review of the 2021 draft PA, the majority of the CASAC advised that the current primary 24-hour $PM_{2.5}$ standard is not adequate and recommended revising the level of the standard, while the minority of the CASAC concluded that the standard was adequate and should be retained. However, in considering the advice of the CASAC collectively in the context of this reconsideration, the Administrator recognizes that the 2021 draft PA included scientific evidence and quantitative risk information that was not available in the 2019 draft PA, and therefore, the advice and recommendations of the CASAC in their review of the 2021 draft PA are based on consideration of the full body of scientific evidence available in this reconsideration, including the evidence evaluated in the 2019 ISA and the ISA Supplement.

The Administrator recognizes that much of the scientific evidence available in this reconsideration was also available in the 2019 ISA and was considered by the then-Administrator when he decided that the current primary $PM_{2.5}$ standards are requisite to protect public health with an adequate margin of safety. However, as described in section I.C.5.b above, in reaching his decision to reconsider the 2020 final decision, the Administrator also recognized that there were a number of studies published since the literature cutoff date of the 2019 ISA that were raised by some members of the CASAC in their review of the 2019 draft PA, in public comments on the 2020 proposal, and in the petitions for reconsideration. As such, the expansion of the air quality criteria in this reconsideration to encompass both the 2019 ISA and the additional scientific evidence evaluated in the ISA Supplement, along with evidence and updated quantitative analyses in the 2022 PA also provided an expanded record for the CASAC's review and public comments as a part of this reconsideration. Taken together, the 2019 ISA, ISA Supplement, and 2022 PA, along with the CASAC's advice and recommendations and public comments, provide the Administrator with additional information for consideration in reaching his final conclusions in this reconsideration. As a result, the record before him notably expands upon and strengthens the basis for the conclusions of the 2019 ISA while reducing some uncertainties that were identified in the 2020 final action.

In considering the available information in this reconsideration, the current Administrator reached different conclusions regarding the appropriate weight to place on certain aspects of the evidence than the then-Administrator in the 2020 final decision. For example, in reaching his conclusions on the primary annual $PM_{2.5}$ standard in 2020, the then-Administrator concluded that it was appropriate to place more weight on epidemiologic studies that used ground-based monitors and to place less weight on the studies that used hybrid model-based approaches, citing to increased uncertainties associated with this new and emerging approach to estimating exposure. In placing more weight on the key U.S. monitor-based studies, the then-Administrator noted that the majority of these studies had mean concentrations at or above the level of the annual standard (12.0 $\mu g/m^3$). However, unlike the approach for considering such studies in the 2012 review, the then-Administrator concluded that it was appropriate to consider the study-reported means collectively, and in so doing, he placed weight on the average of the study-reported means (or medians) across the U.S. monitor-based studies of 13.5 $\mu g/m^3$, and noted that this concentration was above the level of the standard (85 FR 82717, December 18, 2020). In contrast, in this reconsideration, the current Administrator judges that it is appropriate to consider the individual study-reported mean $PM_{2.5}$ concentrations from not only the U.S. monitor-based epidemiologic studies, but also the U.S. hybrid model-based epidemiologic studies, which are an advancement in the available science since the completion of the 2009 ISA. The current Administrator also adopts an approach similar to some previous approaches for the PM NAAQS in which he judges it most appropriate to set the level of the standard to somewhat below the lowest long-term study-reported mean $PM_{2.5}$ concentration reported in key U.S. epidemiologic studies, which is 9.3 $\mu g/m^3$. The study that reports the long-term mean $PM_{2.5}$ concentration of 9.3 $\mu g/m^3$ is newly available in this reconsideration and is evaluated in the ISA Supplement. In the 2019 ISA, the lowest long-term study-reported mean $PM_{2.5}$ concentrations for U.S.-based studies that use ground-based monitors and hybrid model-based approaches are 9.9 $\mu g/m^3$ and 10.7 $\mu g/m^3$, respectively. In judging that it is appropriate to consider both monitor- and hybrid model-based epidemiologic studies and that it is appropriate to adopt an approach to set the level of the standard to somewhat below the lowest long-term mean $PM_{2.5}$ concentration, the current Administrator judges that the available scientific evidence—evaluated in both the 2019 ISA and in the ISA Supplement—provide support for his conclusion that that current primary

$PM_{2.5}$ standard is not adequate and should be revised.

In addition to adopting a different approach than the previous Administrator for considering the long-term mean $PM_{2.5}$ concentrations from key U.S. epidemiologic studies (one more consistent with the approach of the EPA in other prior reviews), the current Administrator both has information newly available in this reconsideration before him and is reaching different conclusions about how to weigh the evidence before him in reaching his final conclusions. For example, in reaching his final decision in 2020, the then-Administrator was concerned about placing too much weight on epidemiologic studies to inform his conclusions on the adequacy of the primary $PM_{2.5}$ standards, noting that the epidemiologic studies do not identify particular $PM_{2.5}$ concentrations that cause effects and cannot alone identify a specific level at which to set the standard. In so doing, the then-Administrator placed greater weight on the uncertainties and limitations associated with the epidemiologic studies, including exposure measurement error, potential confounding by copollutants, increased uncertainty of associations at lower $PM_{2.5}$ concentrations, and heterogeneity of effects across different cities or regions (85 FR 82716, December 18, 2020). The Administrator recognizes that in reaching these judgments, the then-Administrator took into consideration the views of some members of the CASAC, who, in their advice on the 2019 draft PA, expressed the view that the current PM NAAQS should be retained because reported associations between short- and long-term $PM_{2.5}$ exposures and adverse health outcomes ''can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019b, p. 8 of consensus responses).

In this reconsideration, the current Administrator notes that the ISA Supplement evaluates additional studies that employed statistical approaches that attempted to more extensively account for confounders and are more robust to model misspecification (*i.e.,* used alternative methods for confounder control, which are sometimes referred to as causal modeling or causal inference methods) that build upon those studies available and evaluated in the 2019 ISA (U.S. EPA, 2019, sections 11.1.2.1 and 11.2.2.4). These studies report consistent positive associations between long-term and short-term $PM_{2.5}$ exposure and total mortality and cardiovascular effects (U.S. EPA, 2022a, section 3.2.2.3). In considering the epidemiologic evidence evaluated in the 2019 ISA, along with the newly available studies evaluated in the ISA Supplement, the current Administrator also recognizes that there are uncertainties and limitations associated with the epidemiologic studies, but judges that it is appropriate to place less weight on these uncertainties than the then-Administrator placed on them in reaching his final decision in 2020, given the strength of the longstanding large body of epidemiologic evidence, employing a variety of study designs, that demonstrates associations between long- and short-term $PM_{2.5}$ exposures and health effects across multiple U.S. cities and in diverse populations, including in studies examining populations and lifestages that may be at comparatively higher risk of experiencing a $PM_{2.5}$-related health effect (*e.g.,* older adults, children).

In reaching this final decision, the Administrator recognizes he is differing not only with the prior Administrator but also with the advice some members of the CASAC provided during their review of the 2019 draft PA. Specifically, taking into consideration the strength of the evidence providing support for causality determinations, the advice of other members of the CASAC and the need to protect public health with an adequate margin of safety, the current Administrator disagrees with these members of CASAC regarding the weight to be given to epidemiologic evidence ''based on its methodological limitations'' (Cox, 2019b, p. 8 of consensus responses), such as the possibility ''that such associations could reasonably be explained by uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019b, p. 8 of consensus responses).

As another example of information that was not available to the CASAC in providing advice to the Administrator in reaching his final decision in 2020, the then-Administrator noted in his final decision that, while some members of the CASAC and public commenters highlighted a number of accountability studies that examined past reductions in ambient $PM_{2.5}$ concentrations and the degree to which those reductions have resulted in public health improvements, the small number of available accountability studies did not examine air quality with starting concentrations meeting the primary annual $PM_{2.5}$ standard of 12.0 $\mu g/m^3$. The then-Administrator took into consideration the absence of such accountability studies, as part of his consideration of the full body of scientific evidence, in reaching his judgment that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the existing primary $PM_{2.5}$ NAAQS (85 FR 82717, December 18, 2020). However, there are several accountability studies available since the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement in this reconsideration that have starting concentrations (or concentrations prior to the policy or intervention) below 12.0 $\mu g/m^3$ (Corrigan et al, 2018; Henneman et al., 2019; Sanders et al., 2020a). The current Administrator concludes that, while the number of available accountability studies is limited, he recognizes that these studies provide supplemental information for consideration for informing decisions on the appropriate level of the primary annual $PM_{2.5}$ standard along with the full body of evidence.

As EPA has frequently noted throughout this document, the extent to which the current primary $PM_{2.5}$ standards are judged to be adequate depends in part on science policy and public health policy judgments to be made by the Administrator on the strength and uncertainties of the scientific evidence, such as how to consider epidemiologic evidence and the need for an adequate margin of safety in setting the standards. Thus, it would be pure speculation to guess whether the then-Administrator would have reached the same or different conclusions in the 2020 final decision had the record before him included the newly available information in this reconsideration.[107] However, the current Administrator concludes that, for the reasons explained herein that, in his judgment, based on the record before him in this reconsideration, it is necessary and appropriate to revise the primary annual $PM_{2.5}$ NAAQS to provide requisite protection of public health with an adequate margin of safety.

Based on the available scientific evidence and quantitative information, as well as consideration of the CASAC's advice and public comments, the Administrator concludes that the

[107] The EPA notes that, in considering the additional scientific evidence available in this reconsideration, one member of the CASAC who reviewed both the 2019 draft PA and the 2021 draft PA found that the available scientific and quantitative information available in this reconsideration supported revising the level of the primary annual $PM_{2.5}$ standard to within the range of 10–11 $\mu g/m^3$, whereas he recommended retaining the standard during the review of the 2019 draft PA.

current primary annual $PM_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety. In addition, he finds the available information insufficient to call into question the adequacy of the public health protection afforded by the current primary 24-hour $PM_{2.5}$ standard.

In considering how to revise the current suite of primary $PM_{2.5}$ standards in order to achieve the requisite protection for public health, with an adequate margin of safety, against long- and short-term $PM_{2.5}$ exposures the Administrator considers the four basic elements of the NAAQS (indicator, averaging time, form, and level) collectively. With respect to indicator, the Administrator recognizes that the scientific evidence in this reconsideration, as in previous reviews, continues to provide strong support for health effects associated with $PM_{2.5}$ mass. He notes the 2022 PA conclusion that the available information continues to support the $PM_{2.5}$ mass-based indicator and remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components, and too limited to support a distinct standard for the ultrafine fraction of PM (U.S. EPA, 2022b, section 3.6.3.2.1). In its advice on the adequacy of the current primary $PM_{2.5}$ standards in their review of the 2021 draft PA, the CASAC reached consensus that the $PM_{2.5}$ mass-based indicator should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[108] Additionally, there was no information in the public comments that provided a rationale for an alternative indicator. For all of these reasons, the Administrator concludes that it is appropriate to retain $PM_{2.5}$ mass as the indicator for the primary standards for fine particles.

Consistent with his proposed conclusions regarding averaging time, the Administrator notes that the scientific evidence continues to provide strong support for health effect associations with both long- and short-term $PM_{2.5}$ exposures (88 FR 5618, January 27, 2023). Epidemiologic studies continue to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour averaging periods, and associations in epidemiologic studies with subdaily estimates are less consistent and, in some cases, smaller in magnitude (88 FR 5618, January 27, 2023). Taken together, the 2019 ISA concludes that epidemiologic studies do not indicate that subdaily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). In addition, controlled human exposure and panel-based studies of subdaily exposures typically examine subclinical effects rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.,* mortality, hospitalizations). While recent controlled human exposure studies provide consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (*i.e.,* <30 minutes to 5 hours), air quality analyses have shown that the current averaging times can effectively protect against the exposure concentrations in these studies. This information does not indicate that a revision to the averaging time is necessary to provide additional protection against subdaily $PM_{2.5}$ exposures, beyond that provided by the current primary annual and 24-hour $PM_{2.5}$ standards. The Administrator also notes that this conclusion is also support by the CASAC's advice in their review of the 2021 draft PA where they reached consensus that averaging times for the primary $PM_{2.5}$ standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[109] The Administrator also considers the relatively few public comments received that support a subdaily averaging time, but concludes that the currently available information does not provide support for an alternate averaging time. Consistent with his proposed decision, the Administrator concludes that it is appropriate to retain the annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against long- and short-term $PM_{2.5}$ exposures.

With regard to form, the Administrator first notes that the EPA has set both an annual standard and a 24-hour standard to provide protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$ (62 FR 38667, July 18, 1997; 88 FR 5620, January 27, 2023). With regard to the form of the annual standard, the Administrator recognizes that a large majority of the recently available epidemiologic studies continue to report associations between health effects and annual average $PM_{2.5}$ concentrations. These studies of annual average $PM_{2.5}$ concentrations provide support for retaining the current form of the annual standard to provide protection against long- and short-term $PM_{2.5}$ exposures. In its review of the 2021 draft PA, the CASAC reached consensus that the form of the annual standard (*i.e.,* annual mean, averaged over 3 years) should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[110] The Administrator also notes that there were no public comments that recommended an alternative form for the primary annual $PM_{2.5}$ standard.

With regard to the form of the 24-hour standard (98th percentile, averaged over three years), epidemiologic studies continue to provide strong support for health effect associations with short-term (*e.g.,* mostly 24-hour) $PM_{2.5}$ exposures, and controlled human exposure studies provide evidence for health effects following single short-term ''peak'' $PM_{2.5}$ exposures (88 FR 5618, January 27, 2023). Therefore, the Administrator concludes that the evidence supports retaining a standard focused on providing supplemental protection against short-term peak exposures and supports a 98th percentile form for a 24-hour standard, in combination with a primary annual $PM_{2.5}$ standard with its annual mean averaged over three years form. As described in the proposal and in responding to comments in section II.B.3 above, the Administrator further notes that the 98th percentile, averaged over three years, form also provides an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2022b, section 3.6.3.2.3). Furthermore, the Administrator notes that the multi-year percentile form (*i.e.,* averaged over three years) offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. This conclusion is also supported by the CASAC's advice in their review of the 2021 draft PA, where they reached consensus that the form for the primary $PM_{2.5}$ standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).[111]

The Administrator also recognizes that the CASAC recommended that in future reviews, the EPA also consider alternative forms for the primary 24-hour $PM_{2.5}$ standard (Sheppard, 2022a,

[108] The CASAC did not provide advice or recommendations regarding the indicator of the primary $PM_{2.5}$ standards in their review of the 2019 draft PA (Cox, 2019b).

[109] The CASAC did not provide advice or recommendations regarding the averaging times of the primary $PM_{2.5}$ standards in their review of the 2019 draft PA (Cox, 2019b).

[110] The CASAC did not provide advice or recommendations regarding the forms of the primary $PM_{2.5}$ standards in their review of the 2019 draft PA (Cox, 2019b).

[111] The CASAC did not provide advice or recommendations regarding the forms of the primary $PM_{2.5}$ standards in their review of the 2019 draft PA (Cox, 2019b).

p. 18 of consensus responses). Based on the CASAC's advice, the proposal solicited comment on alternatives to the current form for consideration in future reviews (88 FR 5619, January 27, 2023). The Administrator recognizes that there were a limited number of public comments related to the form of the primary $PM_{2.5}$ standards as discussed in section II.D.3 above and in the Response to Comments document, and notes that, the EPA will consider the information provided by the commenters regarding the form of the 24-hour $PM_{2.5}$ standard in the next review of the PM NAAQS. Consistent with his proposed decision, in considering the information summarized above, the Administrator concludes that it is appropriate to retain the forms of the current annual and 24-hour $PM_{2.5}$ standards.

In considering how to revise the current suite of $PM_{2.5}$ standards to provide the requisite public health protection with an adequate margin of safety, the Administrator next evaluates the appropriate levels of the primary $PM_{2.5}$ standards, beginning with the annual $PM_{2.5}$ standard. In having carefully considered public comments related to the primary annual $PM_{2.5}$ standard, the Administrator believes that the fundamental conclusions regarding the scientific evidence and quantitative information that supported his proposed conclusions (as described in the 2019 ISA, ISA Supplement, 2022 PA, and the proposal) remain valid. In considering the level at which the primary annual $PM_{2.5}$ standard should be set, the Administrator considers the entire body of evidence and information, giving appropriate weight to each part of that body of evidence and information. He continues to place the greatest weight in this reconsideration on the available scientific evidence that provides support for associations between health effects and long- and short-term $PM_{2.5}$ exposures. In conjunction with his decisions to retain the current indicator, averaging time, and form as described above, the Administrator is revising the level of the primary annual $PM_{2.5}$ standard to 9.0 $\mu g/m^3$. In so doing, he is selecting a primary annual $PM_{2.5}$ standard that, together with the primary 24-hour $PM_{2.5}$ standard, provides requisite public health protection with an adequate margin of safety, based on his judgments about and interpretation of the scientific evidence and quantitative risk information.

The Administrator's decision to revise the level of the primary annual $PM_{2.5}$ standard to 9.0 $\mu g/m^3$ builds upon his conclusion that the overall body of scientific evidence and quantitative risk information calls into question the adequacy of public health protection afforded by the current standard, particularly for at-risk populations. Consistent with his consideration of the available information in reaching his proposed decisions, the Administrator's final decision on the level of the primary annual $PM_{2.5}$ standard places the greatest emphasis on key U.S. epidemiologic studies that report associations between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity. As in the proposal, and as discussed further below, he views additional epidemiologic studies (*i.e.,* studies that employ alternative methods for confounding control, studies that employ restricted analyses, and accountability studies), the controlled human exposure studies, and the risk assessment as providing supplemental information in support of his decision to revise the current annual standard, but recognizes that some of these lines of evidence and information provide a more limited basis for selecting a particular standard level among a range of options. See *Mississippi,* 744 F. 3d at 1351–52 (studies can legitimately support a decision to revise the standard, but not provide sufficient information to justify their use in setting the level of a revised standard).

Given his consideration of the scientific evidence, quantitative risk information, advice from the CASAC, and public comments, the Administrator judges that a primary annual $PM_{2.5}$ standard with a level of 9.0 $\mu g/m^3$ is requisite to protect public health with an adequate margin of safety. He notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. See *Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62; *Mississippi,* 744 F.3d at 1353. He further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, it is appropriate to consider such factors as the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties present. In considering the need for an adequate margin of safety, the Administrator notes that a primary annual $PM_{2.5}$ standard with a level of 9.0 $\mu g/m^3$ would be expected to provide substantial improvements in public health compared to the current annual standard, including for at-risk groups such as children, older adults, people with preexisting conditions, minority populations, and low SES populations.

Consistent with his conclusions on the need for revision of the current annual standard, in reaching a decision on level, the Administrator places the most weight on information from epidemiologic studies. In so doing, the Administrator notes that these studies provide consistent evidence of positive and statistically significant associations between long- and short-term exposure to $PM_{2.5}$ and mortality and morbidity (88 FR 5624, January 27, 2023). The Administrator recognizes that placing weight on the information from the epidemiologic studies allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a $PM_{2.5}$-related health effects (*e.g.,* children, older adults, minority populations) (88 FR 5624, January 27, 2023). The Administrator also recognizes that recent epidemiologic studies continue to support a no-threshold relationship, meaning that there is no ''bright line'' below which no effects have been found. These studies also support a linear relationship between health effects and $PM_{2.5}$ exposures at $PM_{2.5}$ concentrations greater than 8 $\mu g/m^3$, though uncertainties remain about the shape of the C–R curve at $PM_{2.5}$ concentrations less than 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2; 88 FR 5625, January 27, 2023).

As at the time of proposal, the Administrator notes that some recent epidemiologic studies have adopted a broad range of approaches to examine confounding and the results of those examinations support the robustness of reported associations seen in epidemiologic studies. These include studies that employ alternative methods for confounder control and studies that evaluate the uncertainty related to exposure measurement error, both of which continue to support associations between $PM_{2.5}$ exposures and health effects while taking approaches to address uncertainties.

In considering the epidemiologic evidence, the Administrator judges that, in reaching his decision on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, and in recognizing the need to weigh uncertainties associated with the epidemiologic evidence, it is most appropriate to examine where the evidence of associations observed in the

epidemiologic studies is strongest and, conversely, to place less weight where he has less confidence in the associations observed in the epidemiologic studies. As at the time of proposal, the Administrator notes that in previous reviews, evidence-based approaches noted that the evidence of an association in any epidemiologic study is ''strongest at and around the long-term average where the data in the study are most concentrated'' (78 FR 3140, January 15, 2013). Given this, these approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by previous CASAC advice as well as the CASAC's advice in their review of the 2021 draft PA as a part of this reconsideration.

Additionally, the Administrator acknowledges that in the 2020 final action, the then-Administrator decided to retain the standard based in part on concerns about placing reliance on the epidemiologic studies and his judgment that even if he did rely on them, the majority of the studies had means or medians, as well as the mean of all of the key study-reported means or medians, above the level of the current annual standard. However, after considering the evidence, the advice of CASAC, and public comments the Administrator judges that this approach is insufficient to protect public health with an adequate margin of safety. The Administrator's decision to reach a different judgment about the appropriate level of the annual standard reflects the updated and expanded scientific record available to the Administrator in this reconsideration, as well as the additional advice from the CASAC and the public comments based on this newly available information. In addition, the Administrator observes the decision in this action to place weight on the epidemiologic studies, and to revise the annual primary standard to a level below the lowest long-term mean in the U.S.-based epidemiologic studies, is consistent with the EPA's past practice in PM NAAQS reviews.

In this reconsideration, the Administrator is considering the scientific record which has been expanded and updated since the 2020 final action, as well as the additional advice from the CASAC and the public comments that are based on the newly available information that expands upon the information previously available. In addition, the Administrator is exercising his judgment about how to interpret and weigh the expanded evidence in a way that is more consistent with the approaches used in prior PM NAAQS reviews. As a result, the Administrator has concluded on reconsideration that the level of the primary annual standard is not adequate and should be revised to protect public health with an adequate margin of safety.

Consistent with his proposed decisions, in reaching conclusions on the level of the primary annual $PM_{2.5}$ standard, the Administrator considers the long-term [112] study-reported mean $PM_{2.5}$ concentrations from key long- and short-term epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean $PM_{2.5}$ concentration.[113] He notes that in previous PM NAAQS reviews (including the 1997, 2006 and 2012 reviews), evidence-based approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key long- and short-term epidemiologic studies. These approaches were supported by the CASAC in previous reviews and were supported in this reconsideration by the CASAC in their review of the 2021 draft PA. In considering the available scientific evidence to inform such an approach, the Administrator notes the strength of the epidemiologic evidence which includes multiple studies that consistently report positive associations for short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects. Some available studies also use a variety of statistical methods to control for confounding bias and report similar associations, which further supports the broader body of epidemiologic evidence for both mortality and cardiovascular effects. Additionally, he notes that recent epidemiologic studies available for consideration in reaching his final decision strengthen support for health effect associations at $PM_{2.5}$ concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews. The Administrator does recognize, however, that while these epidemiologic studies evaluate associations between distributions of ambient $PM_{2.5}$ concentrations and health outcomes, they do not identify the specific exposures that led to the reported effects. As such, he notes that there is no specific point in the air quality distribution of any epidemiologic study that represents a ''bright line'' at and above which effects have been observed and below which effects have not been observed. The Administrator further notes that the epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution, and concludes that the long-term study-reported means from both long- and short-term studies provide the strongest support for reported health effect associations in epidemiologic studies. For these reasons, as described in the proposal and in responding to public comments in section II.B.3 above, the Administrator concludes that it is appropriate to continue to employ an approach that focuses on the mean $PM_{2.5}$ concentrations from the key epidemiologic studies to inform his conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard.

In adopting such an approach, the Administrator considers the long-term mean concentrations reported in two types of key epidemiologic studies: (1) Monitor-based studies [114] (epidemiologic studies that used ground-based monitors to estimate exposure, similar to approaches used in past reviews), and (2) hybrid modeling-based studies [115] (epidemiologic studies that used hybrid modeling approaches and apply aspects of population weighting to estimate exposures). In reaching conclusions regarding the level of a standard that would provide requisite protection with an adequate margin of safety, the Administrator recognizes that he must use his judgment regarding the appropriate weight to place on the available evidence and technical information, including uncertainties. As shown in Figures 1 and 2 above, for the key U.S. monitor-based epidemiologic studies,

[112] ''Long-term'' represents $PM_{2.5}$ exposures and concentrations that are annual or multi-year.

[113] As described in section II.A.2.c above, key epidemiologic studies are those that report overall mean (or median) $PM_{2.5}$ concentrations and for which the years of $PM_{2.5}$ air quality data used to estimate exposures overlap entirely with the years during which health events are reported.

[114] Reported mean $PM_{2.5}$ concentrations in monitor-based studies are averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in the study area, referred to as a maximum monitor concentration (*i.e.,* the ''design value'' concentration), which is used to determine whether an area meets a given standard.

[115] Studies that use hybrid modeling approaches employ methods to estimate ambient $PM_{2.5}$ concentrations across large geographical areas, including areas without monitors, and thus, when compared to monitor-based studies, require additional information to inform the relationship between the estimated $PM_{2.5}$ concentrations across an area and the maximum monitor design values used to assess compliance.

the study-reported mean concentrations range from 9.9–16.5 μg/m^3, and for the key U.S. hybrid modeling-based epidemiologic studies, the mean concentrations range from 9.3–12.2 μg/m^3. The Administrator also recognizes that, in their review of the 2021 draft PA, both the majority and minority of the CASAC emphasized the epidemiologic studies in support of their recommendations for the level of the annual standard, but they weighed the studies in different ways (Sheppard, 2022a, p. 16–17 of consensus responses).

Based on this information, and in considering the CASAC's advice in their review of the 2021 draft PA, the Administrator judges that it is appropriate to set the level of the primary $PM_{2.5}$ standard at least as low as the lowest mean $PM_{2.5}$ concentration from these key U.S.-based epidemiologic studies, which is 9.3 μg/m^3. The Administrator additionally notes that setting the annual standard level at 9.0 μg/m^3, which is below the lowest study-reported mean $PM_{2.5}$ concentration of 9.3 μg/m^3, would be expected to shift the distribution of $PM_{2.5}$ concentrations in an area such that the area's highest monitor would generally be at or below 9.0 μg/m^3 annually, when meeting the annual standard. In this situation, the resulting average or mean $PM_{2.5}$ concentration for the entire area (measured across a number of monitors) would be even further below the study-reported means,[116] and will provide adequate protection not only in areas where the highest allowable concentrations would be expected (*i.e.,* near design value monitors) but also in other parts of the area where $PM_{2.5}$ concentrations would be expected to be maintained even lower.

As noted above, however, the Administrator must exercise his judgment regarding the appropriate weight to place on the available scientific evidence and quantitative information, including uncertainties, in determining what level of the annual standard is sufficient to protect public health with an adequate margin of safety. In so doing, he considers other information available in this reconsideration to inform his judgments, including study-reported $PM_{2.5}$ concentrations at lower percentiles in key epidemiologic studies, supplemental information from other types of epidemiologic studies, study-reported $PM_{2.5}$ concentrations from key Canadian epidemiologic studies, and the results from the quantitative risk assessment.

In weighing the evidence in considering the requisite level of the annual standard, the Administrator also takes into account additional information from the key long- and short-term U.S. epidemiologic studies available that provide study-reported $PM_{2.5}$ concentrations below the mean and, in particular, the subset of epidemiologic studies that report 25th and 10th percentile concentrations. Consistent with his proposed conclusions, as well as the CASAC's advice in their review of the 2021 draft PA and public comments, the Administrator judges that it is appropriate to place some weight on these lower percentiles in reaching his conclusions on the level of the primary annual standard. There are six key U.S. epidemiologic studies that report information on other percentiles (*e.g.,* 10th and 25th percentiles of $PM_{2.5}$ concentrations or 10th and 25th percentiles of $PM_{2.5}$ concentrations associated with health events) that are below the mean.[117] In considering the information from these studies, the Administrator first notes that the three older, monitor-based studies that report lower percentiles of $PM_{2.5}$ concentrations have smaller cohort sizes than the three hybrid model-based studies. Thus, the Administrator recognizes that the older, monitor-based studies had a relatively smaller portion of the health events that were observed in the lower part of the air quality distribution because of the generally smaller size of the cohorts. He further notes that the recent hybrid model-based studies have larger cohort sizes than the older, monitor-based studies, and therefore, have more health events in the lower part of the air quality distribution. Because of the larger cohort sizes and having a larger portion of health events that are observed across the air quality distribution, the Administrator has more confidence in the magnitude and significance of the associations in the lower parts of the air quality distribution for the recent, hybrid model-based studies compared to the older, monitor-based studies. Given this, the Administrator judges that it is appropriate to place weight on the 25th percentile concentrations reported in the recently available hybrid model-based studies in reaching his conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard. However, the Administrator also recognizes that his confidence in the magnitude and significance in the reported concentrations, and their ability to inform decisions on the appropriate level of the annual standard, starts to diminish at percentiles that are even further below the mean and the 25th percentile. For these reasons, the Administrator places weight on the reported 25th percentiles concentrations in the recent hybrid model-based studies, rather than the reported 10th percentile concentrations, in reaching his conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard.

In considering the information from these studies, as described in section II.A.2.c and in responding to public comments in section II.B.3 above, the Administrator notes that there are two hybrid model-based studies with large cohort sizes that apply population weighting and report lower percentile values. These studies are Di et al. (2017b) and Wang et al. (2017) and the reported 25th percentile concentration is 9.1 μg/m^3 for both studies.[118] In considering these studies, the Administrator concludes that it is appropriate to place weight on the 25th percentile concentrations of these newer hybrid model-based studies (of 9.1 μg/m^3) such that setting the level of the standard near these 25th percentile concentrations would provide requisite protection. The Administrator observes that an annual standard level of 9.0 μg/m^3 would be near the reported 25th percentile concentrations in these studies.

As at the time of proposal, the Administrator also takes note of the study-reported long-term mean $PM_{2.5}$ concentrations in long- and short-term Canadian epidemiologic studies, which ranged from 6.9 to 13.3 μg/m^3 for monitor-based studies and 5.9 to 9.8 μg/m^3 for hybrid model-based studies. While the Administrator notes that these studies provide additional support for associations between $PM_{2.5}$ concentrations and health effects, he is also mindful that there are important differences between the exposure environments in the U.S. and Canada and that interpreting the data (*e.g.,* study-reported mean concentrations)

[116] Analyses in the 2022 PA suggest that the highest monitored value would be expected to be greater than the study-reported mean values by 10–20% for monitor-based studies and 15–18% for hybrid modeling studies that apply aspects of population weighting.

[117] The Wang et al. (2017) study only reports the 25th percentile of the estimated $PM_{2.5}$ concentrations, not the 10th percentile.

[118] There is a third hybrid model-based study, as described in the 2022 PA and in section II.B.3 above in responding to public comments, but it is not referenced here because it reports a 25th percentile $PM_{2.5}$ concentration based on the 25th percentile of health events that occur in the study (Di et al., 2017a) rather than report the 25th percentile based on air quality concentrations.

from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing decisions regarding potential alternative levels of the annual standard. For example, in terms of people per square kilometer, the U.S. population density is nearly 10 times in the contiguous U.S. compared to Canada. As described in more detail in responding to public comments in section II.B.3 above, in this reconsideration, the Administrator recognizes that this difference in population density between the U.S. and Canada is more apparent than in previous reviews because the studies available in this reconsideration use different approaches than those previously available. In the 2012 review, the available Canadian epidemiologic studies used population-weighting and focused on urban areas where monitors were available and population densities were more comparable with those in the U.S., and at that time, the U.S. and Canadian studies reported similar mean $PM_{2.5}$ concentrations. However, in this reconsideration, the Administrator takes note that for the new Canadian epidemiologic studies: (1) The Canadian monitor-based studies available in this reconsideration do not apply population weighting as the previously available studies did; and (2) some of the studies now use hybrid modeling approaches for estimating exposure. The Administrator recognizes that these differences are important to consider in reaching conclusions on how these Canadian epidemiologic studies should be interpreted regarding decisions on the requisite level of the primary annual $PM_{2.5}$ standard. Specifically, the Administrator notes that the more recent Canadian studies that use hybrid modeling incorporate larger portions of the country, and therefore include more rural areas. The more rural areas that are included in the study using the hybrid modeling approaches, the more important it is to consider how the population densities and exposure environments differ between the U.S. and Canada. Additionally, the Administrator notes that for hybrid modeling-based studies there is less certainty in $PM_{2.5}$ exposure estimates in more rural areas, which are further from air quality monitors and where $PM_{2.5}$ concentrations in the ambient air tend to be lower. For these hybrid model-based studies, the portion of the rural areas that are contributing to the study-reported mean $PM_{2.5}$ concentrations in these studies is unclear. For these reasons, the Administrator concludes that it is important to consider the differences between the population exposures in the U.S. and Canadian study areas and how these differences influence the interpretation of the epidemiologic study results.

Thus, the Administrator considers the Canadian studies to inform his judgments on what level for the annual standard is requisite in light of the limitations and challenges presented. The Administrator also recognizes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, place weight on the Canadian epidemiologic studies in recommending that the level of the primary annual $PM_{2.5}$ standard be revised to 8–10 $\mu g/m^3$. The Administrator further notes while the majority of the CASAC advised the EPA to consider the Canadian studies in revising the annual standard level to within the range of 8.0–10.0 $\mu g/m^3$, they did not advise the EPA to set the annual standard level below the study-reported means from those studies. Given these considerations, the Administrator judges that it is appropriate to set the level of annual standard within the range of 8–10 $\mu g/m^3$ to be consistent with the majority of the CASAC's advice in their consideration of these studies.

The Administrator also recognizes that information from epidemiologic studies that included analyses that restrict annual average $PM_{2.5}$ concentrations to concentrations below the level of the current annual standard can be useful for informing conclusions regarding the appropriate level of the primary annual $PM_{2.5}$ standard. In so doing, he particularly notes the two key U.S. epidemiologic studies (Di et al., 2017b and Dominici et al., 2019) that restrict annual average $PM_{2.5}$ concentrations to less than 12 $\mu g/m^3$ and report positive and statistically significant associations with all-cause mortality and mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. He also considers these results along with the uncertainties and limitations associated with studies that restricted analyses below certain $PM_{2.5}$ concentrations. As described in responding to comments in section II.B.3 above, uncertainties associated with how the studies exclude $PM_{2.5}$ concentrations from the analyses (*e.g.,* at what spatial resolution are concentrations being excluded), make it difficult to understand how to interpret the results of the restricted analyses in the context of the approach employed in this reconsideration, which takes into consideration the relationship between mean $PM_{2.5}$ concentrations and design values.

The Administrator also recognizes that, in their review of the 2021 draft PA, the CASAC noted that epidemiologic studies that restrict analyses below certain $PM_{2.5}$ concentrations represent one area for which the evidence has expanded in this reconsideration, stating that these studies provide support for mortality effects at concentrations below the current PM NAAQS (Sheppard, 2022a, p. 5 of consensus responses). In their recommendations on alternative levels for the primary annual $PM_{2.5}$ standard, the majority of the CASAC cited to studies that restrict $PM_{2.5}$ concentrations to below 12 $\mu g/m^3$ as a part of their rationale for supporting a level within the range of 8–10 $\mu g/m^3$ (Sheppard, 2022a p. 16 of consensus responses). Additionally, the Administrator notes that some members of the CASAC, in their review of the 2019 draft PA, concluded that the epidemiologic studies that restrict analyses below 12 $\mu g/m^3$ and show positive associations with health effects, along with other aspects of the scientific evidence, provide support for their conclusion that the primary annual $PM_{2.5}$ standard is not adequate (Cox, 2019b, p. 9 of consensus responses). Furthermore, the Administrator takes note of public commenters who also noted that the epidemiologic studies that restrict $PM_{2.5}$ concentrations to below the current standard provide support, along with the other available information, for lowering the level of the primary annual $PM_{2.5}$ standard. In considering the studies that include restricted analyses, along with the CASAC's advice and public comments on these types of studies, the Administrator concludes that, although there are inherent uncertainties associated with this limited body of evidence, these studies that apply restricted analyses provide support for serious effects (*e.g.,* mortality) at concentrations below 10.0 $\mu g/m^3$. Given this, the Administrator concludes that it is appropriate to place some weight on these studies, and in doing so, notes that a standard level of 9.0 $\mu g/m^3$ would be below the reported mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$ in these studies and would, thus, be expected to provide protection against exposures related to these reported mean concentrations.

The Administrator also takes into consideration recent U.S. accountability studies, which assess the health effects associated with actions that improve air quality (*e.g.,* air quality policies or implementation of an intervention). These types of studies can also reduce uncertainties related to residual confounding of temporal and spatial factors (U.S. EPA, 2022a, p. 3–25). The

Administrator notes that in the 2020 review, the available accountability studies had ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* mean concentration prior to reductions being evaluated) from 13.2–31.5 μg/m³, and the then-Administrator cited the lack of accountability studies in areas where the ''starting'' concentration met the current primary $PM_{2.5}$ standards as part of his rationale for retaining the standards. As at the time of proposal, the current Administrator notes that in three studies newly available in this reconsideration and assessed in the ISA Supplement, prior to implementation of the policies, mean $PM_{2.5}$ concentrations in these studies were below the level of the current annual standard level (12.0 μg/m³) and ranged from 10.0 μg/m³ to 11.1 μg/m³. These studies report positive and significant associations between mortality and cardiovascular morbidity and reductions in ambient $PM_{2.5}$ following the implementation of a policy (Henneman et al., 2019; Corrigan et al., 2018; Sanders et al., 2020a; 88 FR 5627, January 27, 2023). These studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 μg/m³. The Administrator recognizes that in their review of the 2021 draft PA, the CASAC noted that the availability of recent accountability studies was one area where the evidence had been strengthened and that the studies assessed in the ISA Supplement provide evidence of mortality effects at annual average $PM_{2.5}$ concentrations below the current NAAQS (Sheppard, 2022a, p. 5 of consensus responses). The Administrator recognizes that the CASAC also concluded that, along with other lines of evidence, the accountability studies with starting concentrations below the levels of the current standards are appropriate to consider for informing conclusions on alternative standard levels (Sheppard, 2022a, p. 13 of consensus responses). The Administrator also notes the advice of the CASAC in their review of the 2019 draft ISA, where they suggested that accountability studies be taken into account and such studies provide potentially crucial information about whether and how much decreasing $PM_{2.5}$ causes decreases in future health effects, which reflects the primary purpose of the NAAQS (Cox, 2019b, p. 8 and 10 of consensus responses). The Administrator also notes that in their review of the 2019 draft ISA, some members of the CASAC cautioned against placing more weight on the data from accountability studies based on the methodological limitations of the studies (Cox, 2019b, p. 8 of consensus responses). The Administrator notes that the CASAC did not explicitly cite to accountability studies in their reviews of the 2019 draft PA or 2021 draft PA as support for their recommendations on the adequacy of the primary annual $PM_{2.5}$ standard or potential alternative standard levels. A number of public commenters who support revising the level of the standard to 8 μg/m³ cite these accountability studies, along with the broader evidence base, as support for a more protective standard. The Administrator, in considering the evidence, the advice from the CASAC, and public comment, first recognizes that accountability studies are just one line of evidence to be considered in the broader evaluations of the information available to inform conclusions on the level of the standard. In so doing, he notes that public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 μg/m³, and potentially below the lowest ''starting'' concentrations in these studies of 10.0 μg/m³. However, the Administrator concludes that the limited number of accountability studies provide limited information for informing decisions on the appropriate level of the primary annual $PM_{2.5}$ standard but recognizes that these studies provide supplemental information for consideration along with the full body of evidence. Taken together, the Administrator notes a revised annual standard level of 9.0 μg/m³ is at or below the lowest starting concentration of these accountability studies (*i.e.,* 10.0 μg/m³), and judges that it is appropriate to place some weight on these studies, particularly for informing his public policy judgments regarding an adequate margin of safety.

In addition to his consideration of and conclusions regarding the available scientific evidence, the Administrator also considers the results of the quantitative risk assessment to inform his conclusions regarding the appropriate level for the primary annual $PM_{2.5}$ standard. The Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context, but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. The Administrator recognizes that the overall risk assessment estimates suggest that the current primary annual $PM_{2.5}$ standard could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. The Administrator also recognizes that the CASAC concurred with the 2021 draft PA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard (Sheppard, 2022a, p. 16 of consensus responses).

Additionally, with respect to the results of the quantitative risk assessment, the Administrator recognizes that the 2022 PA also provides information on the distribution of concentrations associated with the estimated mortality risk at each alternative standard level assessed (U.S. EPA, 2022b, sections 3.4.2.2 and 3.6.2.2, Figure 3–18 and 3–19). When meeting an annual standard of 9.0 μg/m³ at the design value monitor, the exposure concentrations within an area are estimated to be below 9 μg/m³, with the majority of those exposures being at concentrations of below 8 μg/m³. The Administrator notes that this range of concentrations is below the lowest means in the key long- and short-term epidemiologic studies (concentrations at which the evidence is the strongest in supporting an association between exposure to $PM_{2.5}$ and adverse health effects observed in the key epidemiologic studies available in this reconsideration). Thus, the Administrator concludes that the results of the quantitative risk assessment suggest that a revised annual standard level of 9.0 μg/m³ is estimated to reduce $PM_{2.5}$ exposures to fall within the range of concentrations in which there is the most confidence in the associations and thus, confidence that estimated risk reductions will actually occur.

The Administrator also notes the information provided by the quantitative risk assessment on the distribution of concentrations associated with the estimated mortality risk for a higher annual standard level of 10.0 μg/m³ and a lower standard level of 8.0 μg/m³ (U.S. EPA, 2022b, sections 3.4.2.2 and 3.6.2.2, Figure 3–18 and 3–19). The Administrator finds that, for an annual standard level of 10.0 μg/m³, the quantitative risk assessment estimates that the standard would allow multiple exposures at concentrations above the lowest means in the key epidemiologic studies, and therefore, calls into question whether a standard level of 10.0 μg/m³ would provide enough public health protection. Additionally, the Administrator also finds that, for a lower annual standard level of 8.0 μg/

m^3, the quantitative risk assessment estimates the exposure concentrations to be below 8 $\mu g/m^3$, with the majority of those exposures being at concentrations of below 7 $\mu g/m^3$. The Administrator observes that the majority of exposure concentrations under this air quality scenario are estimated to fall outside of the range of concentrations in which he has the most confidence in the associations and that the additional risk reductions will actually occur.

Recognizing and building upon the above considerations and judgments, and with consideration of advice from the CASAC and public comment, the Administrator concludes that the current body of scientific evidence and quantitative risk assessment support his judgment that the level of the primary annual $PM_{2.5}$ standard should be revised to a level of 9.0 $\mu g/m^3$. Revising the level of the primary annual $PM_{2.5}$ standard will, in the Administrator's judgment, provide requisite public health protection with an adequate margin of safety.

The Administrator recognizes that placing weight on the information from the epidemiologic studies allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a $PM_{2.5}$-related health effects (*e.g.,* children, older adults, minority populations) (88 FR 5624, January 27, 2023). In considering the epidemiologic evidence, the Administrator judges that, in reaching his decision on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, and in recognizing the need to weigh uncertainties associated with the epidemiologic evidence, it is most appropriate to examine where the evidence of associations observed in the epidemiologic studies is strongest and, conversely, to place less weight where he has less confidence in the associations observed in the epidemiologic studies. The Administrator notes that in previous reviews, evidence-based approaches noted that the evidence of an association in any epidemiologic study is ''strongest at and around the long-term average where the data in the study are most concentrated'' (78 FR 3140, January 15, 2013). These approaches were supported by previous CASAC advice as well as the CASAC's advice in their review of the 2021 draft PA as a part of this reconsideration. Given this, the Administrator notes that in revising the annual $PM_{2.5}$ standard to a level of 9.0 $\mu g/m^3$, he is setting the standard at a level below the long-term mean $PM_{2.5}$ concentrations in the key long- and short-term epidemiologic studies, including the lowest study reported mean of 9.3 $\mu g/m^3$, following an approach that is consistent with previous PM NAAQS reviews. The Administrator additionally notes that air quality analyses in the 2022 PA demonstrate that areas meeting a revised annual standard of 9.0 $\mu g/m^3$ would be expected to shift the distribution of $PM_{2.5}$ exposure concentrations in an area such that the area's highest monitor would generally be at or below 9.0 $\mu g/m^3$ annually, and most of the resulting $PM_{2.5}$ concentrations across the area would be even further below the study-reported means.[119] [120] Thus, a standard level of 9.0 $\mu g/m^3$ is expected to provide sufficient protection not only in areas where the highest allowable concentration would be located (*i.e.,* near design value monitors) but also in other parts of the area where $PM_{2.5}$ concentrations would be expected to be maintained even lower.

Furthermore, the Administrator recognizes the CASAC's advice in their review of the 2021 draft PA, as well as public comments, that weight should be placed on study-reported $PM_{2.5}$ concentrations that are somewhat below the mean, particularly for some of the newer epidemiologic studies with larger cohort sizes. In weighing uncertainties associated with using these data to inform a revised annual standard level, as well as noting the limited studies for which this information is available, the Administrator judges that some weight should be placed on these data, but they should not receive the same weight as the study-reported mean concentrations. Thus, the Administrator concludes that it would be appropriate to set the annual standard level near the 25th percentile $PM_{2.5}$ concentrations in the two newer key epidemiologic studies for which these values were reported. In doing so, the Administrator notes that a decision to revise the annual standard to 9.0 $\mu g/m^3$ would set a level of the standard near and somewhat below the reported 25th percentile $PM_{2.5}$ concentrations of 9.1 $\mu g/m^3$ in these two more recent hybrid model-based studies.

The Administrator also takes note of the study-reported long-term mean $PM_{2.5}$ concentrations in the key Canadian epidemiologic studies. While the Administrator notes that these studies provide additional support for associations between $PM_{2.5}$ concentrations and health effects, he is also mindful that there are important differences between the exposure environments in the U.S. and Canada that affect interpretation of the data in the context of informing decisions regarding potential alternative levels of the annual standard. The Administrator also recognizes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, placed weight on the Canadian epidemiologic studies in recommending that the level of the primary annual $PM_{2.5}$ standard be revised to 8–10 $\mu g/m^3$. The Administrator notes that a decision to revise the annual standard to 9.0 $\mu g/m^3$ would set the level of the standard within the range of levels recommended by the majority of CASAC in their consideration of these studies.

Additionally, the Administrator also considers the information provided by epidemiologic studies that use restricted analyses, as well as accountability studies. With respect to the restricted analyses, the Administrator, in considering the CASAC's advice in their review of the 2021 draft PA and many public comments on these types of studies, concludes that, although there are inherent uncertainties associated with this limited body of evidence, the studies that apply restricted analyses provide support for serious effects (*e.g.,* mortality) at concentrations below 10.0 $\mu g/m^3$. Additionally, in considering accountability studies, the Administrator concludes that while the small number of these studies provide limited information for informing decisions on the appropriate level of the primary annual $PM_{2.5}$ standard, these studies provide supplemental information for consideration along with the full body of evidence. The Administrator further notes that these studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 $\mu g/m^3$, and potentially below the lowest ''starting'' concentrations in these studies of 10.0 $\mu g/m^3$. Taken together, the Administrator judges that it is appropriate to place some weight on these types of studies, particularly for informing his public policy judgments regarding an adequate margin

[119] Analyses in the 2022 PA suggest that the highest monitored value would be expected to be greater than the study-reported mean values by 10–20% for monitor-based studies and 15–18% for hybrid modeling studies that apply aspects of population weighting (U.S. EPA, 2022b, section 2.3.3.2.4).

[120] The risk assessment in the 2022 PA used air quality adjustments to simulate just meeting the current primary $PM_{2.5}$ standards, as well as alternative standard levels (U.S. EPA, 2022b, section 3.4.1.4 and Appendix C, section C.1.4).

of safety, and notes that a revised annual standard level of 9.0 μg/m³ is below the lowest starting concentration of the accountability studies (*i.e.,* 10.0 μg/m³), and below the concentration at which studies that apply restricted analyses provide support for serious effects (*i.e.,* 9.6 μg/m³).

The Administrator also judges that the results of the quantitative risk assessment provide support for a primary annual $PM_{2.5}$ standard with a level of 9.0 μg/m³. The results of the risk assessment suggest that when meeting an annual standard of 9.0 μg/m³, $PM_{2.5}$ exposures are maintained below 9 μg/m³ at the design value monitor, with the majority of those exposures being at concentrations below 8 μg/m³. Thus, the Administrator notes that an annual standard level of 9.0 μg/m³ would be expected to provide protection from exposures where he has the greatest confidence in the associations between health effects and $PM_{2.5}$ exposures (*i.e.* the long-term mean $PM_{2.5}$ concentrations in the key U.S. epidemiologic studies, of which the lowest is 9.3 μg/m³) and would provide an adequate margin of safety by maintaining most $PM_{2.5}$ exposures even further below 9.0 μg/m³.

When considering adequate margin of safety, the Administrator notes that in his decision to revise the annual standard level to 9.0 μg/m³, he is placing weight on the information from the epidemiologic studies which allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a $PM_{2.5}$-related health effects (*e.g.,* children, older adults, minority populations). Additionally, as discussed above, the Administrator also recognizes that setting the annual standard level at 9.0 μg/m³, which is below concentrations at which the evidence is the strongest in supporting an association between exposure to $PM_{2.5}$ and adverse health effects observed in the key epidemiologic studies available in this reconsideration, would be expected to shift the distribution of $PM_{2.5}$ exposure concentrations in an area such that the area's highest monitor would generally be at or below 9.0 μg/m³ annually, and most of the resulting $PM_{2.5}$ concentrations across the area would be even lower. In considering these air quality relationships, the Administrator judges that a revised annual standard level of 9.0 μg/m³ would provide requisite protection with adequate margin of safety, for all populations, including those most at-risk.

In reaching this conclusion, the Administrator recognizes that in establishing primary standards under the Act that are requisite to protect public health with an adequate margin of safety, he is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that avoids unacceptable risks to public health. In this context, the Administrator's conclusion is that revised primary annual standard, in conjunction with the 24-hour standard, provides the appropriate degree of protection, and that more or less stringent standards would not be requisite.

In considering the requirement for an adequate margin of safety, the Administrator notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. *See Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62; *Mississippi,* 744 F.3d at 1353. He further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, it is appropriate to consider such factors as the nature and severity of the health effects, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties present. Consistent with past practice and long-standing judicial precedent, and as described in this section, the Administrator takes the need for an adequate margin of safety into account as an integral part of his decision making on a standard. *See, e.g., NRDC* v. *EPA,* 902 F. 2d 962, 973–74 (D.C. Cir. 1990).

Given all of the evidence and information discussed above, the Administrator judges that a standard with a level of 9.0 μg/m³ is requisite to protect public health with an adequate margin of safety. In so doing, he first recognizes that a less stringent standard would allow the occurrence of higher long- and short-term $PM_{2.5}$ concentrations at a level at or above the mean $PM_{2.5}$ concentrations in key U.S. epidemiologic studies. That is, a less stringent standard would be expected to allow more $PM_{2.5}$ exposures at concentrations at or above which the key U.S. epidemiologic studies have reported associations between mean $PM_{2.5}$ concentrations and serious health effects and would deviate from some past approaches for selecting the appropriate level of the annual standard. A less stringent standard would also not provide requisite protection with an adequate margin of safety against $PM_{2.5}$ exposures in the lower percentiles of the air quality distribution (*i.e.,* 25th percentile) for which associations with health effects have been observed in a limited number of epidemiologic studies. Furthermore, the Administrator notes that the primary annual and 24-hour $PM_{2.5}$ standards, together, are intended to provide public health protection against the full distribution of long- and short-term $PM_{2.5}$ exposures. As noted above, the Administrator recognizes that the changes in $PM_{2.5}$ air quality designed to meet a less stringent annual standard would likely result in higher exposures across the distribution of air quality, including both higher average (or typical) concentrations as well as higher short-term peak $PM_{2.5}$ concentrations. Taking into consideration both the full evidence base for associations of $PM_{2.5}$ with mortality and other adverse health effects, including the reported mean $PM_{2.5}$ concentrations from key long- and short-term U.S. epidemiologic studies, information from epidemiologic studies that report 25th percentile $PM_{2.5}$ concentrations, supplemental information from other epidemiologic studies (*i.e.,* epidemiologic studies that use restricted analyses, accountability studies, and Canadian epidemiologic studies), and the results of the risk assessment, as well as the advice from the CASAC and public comments, the Administrator concludes that a less stringent standard would allow risks of mortality and other adverse health effects that are too great, and thus would not provide sufficient protection for public health as required by the CAA.

Additionally, in considering a less stringent standard, the Administrator recognizes that through its control of long- and short-term $PM_{2.5}$ concentrations, the annual standard provides a margin of safety for less well-studied exposure levels and population groups for which the evidence is limited or lacking. In so doing, he recognizes that our understanding of the relationships between the presence of a pollutant in ambient air and associated health effects is based on a broad body of information encompassing not only more established aspects of the evidence, such as the conclusion that long- and short-term exposures to $PM_{2.5}$ are causally related to mortality and cardiovascular effects and likely to be causally related to respiratory effects, but also aspects with which there may be substantial uncertainty. In particular, the Administrator notes that there are other categories of effects with causality determinations that are suggestive of, but not sufficient to infer, a causal

relationship between $PM_{2.5}$ exposure and health outcomes. These include, but are not limited t,o short-term exposure and nervous system effects, as well as long- and short-term exposure and pregnancy and birth outcomes, where the evidence is less certain but which represent potentially substantial additional risk to public health from exposure to $PM_{2.5}$. He recognizes the CAA requirement that requires primary standards to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information as well as to provide a reasonable degree of protection against hazards that research has not yet identified and in his judgment, the primary NAAQS must be set at a level that is adequately protective against these and other effects which research has not yet identified. Thus, even if the Administrator had somewhat greater concerns about the possibility of confounding, error and bias in the epidemiologic studies, which reduced his confidence in finding that $PM_{2.5}$ is causally related to mortality and cardiovascular effects, he would still find it appropriate to set the primary NAAQS below the means of key U.S. epidemiologic studies given the strength of the evidence providing support for the association, as well as additional evidence linking $PM_{2.5}$ to other endpoints of substantial public health concern, and the need to protect public health with an adequate margin of safety. In considering the uncertainties in both the epidemiologic evidence and the controlled human exposures studies, the Administrator recognizes that collectively, the health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. In light of these uncertainties, the Administrator recognizes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. The Administrator has taken the need to provide for an adequate margin of safety into account as an integral part of his decision-making on the appropriate standards in setting the standard at a level below the level where available epidemiologic studies, which include diverse populations that are broadly representative of the U.S. population including at-risk populations, have provided the strongest evidence supporting effects, and in other ways as well. For example, consideration of a margin of safety is reflected in the approach of setting the level of the annual standard near and somewhat below the 25th percentile $PM_{2.5}$ concentrations from key U.S. epidemiologic studies (*i.e.,* 9.1 $\mu g/m^3$), as well as recognition that attaining a design value will generally result in significantly broader and greater improvements of air quality across an area (including but certainly not limited to areas near the design value monitor) (U.S. EPA, 2022a, sections 2.3.3.2.4 and 3.3.3.2.1, Table 3–5). Based on all of the considerations noted here, and considering the current body of evidence, including the associated limitations and uncertainties, in combination with the exposure/risk information, the Administrator concludes that a less stringent standard than the current standard would not provide the requisite protection of public health, including an adequate margin of safety.

Having concluded that a less stringent standard would not provide the requisite protection of public health, the Administrator next considers whether a more stringent standard would be appropriate. In so doing, he notes that a decision to set the level of the annual standard to below 9.0 $\mu g/m^3$ would place a large amount of the emphasis on potential public health importance of further reducing the occurrence of $PM_{2.5}$ concentrations of concern, though the exposures about which he is most concerned are well controlled with an annual standard level of 9.0 $\mu g/m^3$, as demonstrated by the quantitative risk assessment. Such a decision would also place greater weight on (1) further reducing ambient $PM_{2.5}$ concentrations relative to those observed in long-and short-term epidemiologic studies, including those that he had judged to have significant uncertainties, including Canadian studies, studies using restricted analyses, and accountability studies; (2) shifting the air quality distribution in areas such that the highest exposure concentrations are reduced to below $PM_{2.5}$ concentrations observed in epidemiologic studies to be in the 25th or lower percentile, for which the evidence is limited; and (3) further shifting exposure concentrations to those shown at the lower end of the distribution in the quantitative risk assessment, despite the important uncertainties in the overall risk assessment. As discussed in this section and in responses to significant comments above and in the Response to Comments document, the Administrator has concluded that placing a large emphasis on these factors and revising the standard to a level below 9.0 $\mu g/m^3$ would result in a standard that is more stringent than the evidence indicates to be sufficient to protect public health with an adequate margin of safety. Compared to a primary annual $PM_{2.5}$ standard set at a level of 9.0 $\mu g/m^3$, the Administrator concludes that the extent to which lower standard levels could result in further public health improvements becomes notably less certain.

Thus, having carefully considered the scientific evidence, quantitative information, CASAC advice, and public comments relevant to his decision on the level of the primary annual $PM_{2.5}$ standard, as discussed above and in the Response to Comments document, the Administrator is revising the level of the primary annual $PM_{2.5}$ standard to 9.0 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence and information, an annual standard set at this level and using the specified indicator, averaging time, and form, in conjunction with the other primary PM standards, would be requisite to protect public health with an adequate margin of safety. The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of at-risk populations, including children, older adults, those with pre-existing cardiovascular and respiratory diseases, minority populations, and low SES populations. The Administrator believes that a standard set at 9.0 $\mu g/m^3$ would be sufficient to protect public health with a margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection. This judgment by the Administrator appropriately considers the degree of protection that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In reaching his conclusions on adequacy of the current suite of primary $PM_{2.5}$ standards, based on consideration of the available scientific evidence and quantitative information, the CASAC's advice and public comments, the Administrator finds that the available information is insufficient to call into question the adequacy of the public

health protection afforded by the current primary 24-hour $PM_{2.5}$ standard. As described earlier in this section, the Administrator concludes that it is appropriate to retain the current indicator ($PM_{2.5}$), averaging time (24-hour), and form (98th percentile, averaged over three years) for the primary 24-hour $PM_{2.5}$ standard and below explains the basis for his final decision that is also appropriate to retain the current level of the primary 24-hour $PM_{2.5}$ standard.

In reaching his conclusion to retain the current primary 24-hour $PM_{2.5}$ standard the Administrator does so in light of the conclusion that the epidemiologic evidence supports associations between short- and long-term $PM_{2.5}$ exposures and adverse health effects, but that the epidemiologic evidence does not identify specific concentrations at which those effects occur and the Administrator has greatest confidence in effects where the bulk of the data is reported (*i.e.,* the mean $PM_{2.5}$ concentration, with some consideration for the 25th percentile of the air quality distribution). Thus, in considering the epidemiologic evidence, the Administrator concludes it is appropriate to focus on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, and that it is appropriate to revise the level of the annual standard level to 9.0 $\mu g/m^3$. In addition to the epidemiologic evidence, the Administrator also considers the available controlled human exposure studies, which provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations that typically correspond to upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). In so doing, the Administrator notes that these studies report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ and at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies. In particular, the Administrator notes that a single study is assessed in the ISA Supplement that reports effects following 4-hour exposures at 37.8 $\mu g/m^3$, although the results of this study are inconsistent with the results of the controlled human exposure studies assessed in the 2019 ISA. Along with the inconsistent results from the controlled human exposure studies, the Administrator also recognizes that effects observed in these studies are intermediate effects which are not typically considered adverse and that the study participants were healthy individuals. Taking into consideration the available scientific evidence, including the uncertainties and limitations, along with the CASAC's advice, the Administrator concludes that it is appropriate to maintain a primary 24-hour $PM_{2.5}$ standard to protect against peak exposures.

Thus, the Administrator considers what primary 24-hour $PM_{2.5}$ standard is requisite to provide supplemental protection against peak exposures. While having confidence that the revised annual standard will result in lowering risk associated with both long- and short-term $PM_{2.5}$ exposure by lowering the overall air quality distribution, as in the 2012 review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term $PM_{2.5}$ exposures in all parts of the country. Therefore, he continues to conclude that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard, in conjunction with a revised annual standard level of 9.0 $\mu g/m^3$.

In considering the available scientific evidence assessed in the 2019 ISA and ISA Supplement, the Administrator first considers the controlled human exposure studies for informing his decisions on the primary 24-hour $PM_{2.5}$ standard. In so doing, he notes that in their review of the 2021 draft PA, the majority of CASAC members expressed the view that controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard without revision, in part because these studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours. Thus, in the view of the majority, ''the evidence of effects from controlled human exposure studies with exposures close to the current 24-hour standard supports epidemiological evidence for lowering the standard'' (Sheppard, 2022a, p. 3–4 of consensus letter). In reviewing the controlled human exposure studies, the Administrator agrees with the majority of CASAC that these controlled human exposure studies generally do not include populations with substantially increased risk from exposure to $PM_{2.5}$, such as children, older adults, or those with more severe underlying illness. However, he disagrees with any conclusion that they should not be used to inform a decision about the adequacy of the current standard. The Administrator finds the information available from these studies to be useful, noting that the recently available controlled human exposure studies provide evidence for health effects following single, short-term exposures to $PM_{2.5}$ concentrations that are greater than those allowed under the current standard. The results of the controlled human exposure studies are inconsistent, particularly at lower $PM_{2.5}$ concentrations, but some studies do report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (and at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). Additionally, one controlled human exposure study assessed in the ISA Supplement reports evidence of some effects for cardiovascular markers following 4-hour exposures to 37.8 $\mu g/m^3$ (Wyatt et al., 2020). However, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA. The Administrator finds these studies are important in establishing biological plausibility for $PM_{2.5}$ exposures causing more serious health effects, such as those seen in short-term exposure epidemiologic studies, and they provide support that more adverse effects may be experienced following longer exposure durations and/or exposure to higher concentrations. As described in more detail in responding to public comments in section II.B.3 above, he notes that although the controlled human exposure studies do not provide a threshold below which no effects occur, the observed effects in these controlled human exposures studies are ones that signal an intermediate effect in the body, likely due to short-term exposure to $PM_{2.5}$, and typically would not, by themselves, be judged as adverse. As noted in sections II.A.2 and II.B.3 above, associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants in previous NAAQS reviews have been informed by guidance, criteria or interpretative statements developed within the public health community. This type of information on adversity of effects is particularly informative to the Administrator's judgments regarding the adversity of the effects observed in the controlled human exposure studies which are short-term in nature (*i.e.,* generally ranging from 2- to 5-hours), including those studies that are

conducted at near-ambient $PM_{2.5}$ concentrations. Based on the observation that the effects observed in Wyatt et al. (2020) are not by themselves adverse, and the fact that the findings of this study are inconsistent with other currently available evidence regarding the level at which effects are observed, the Administrator disagrees with the view expressed by the majority of CASAC that this study supports epidemiologic evidence for lowering the 24-hour standard.

Consistent with his approach in reaching his proposed decision and taking into consideration these points as well as balancing these limitations (*i.e.,* that the health outcomes observed in these controlled human exposure studies are not clearly adverse and that the studies generally do not include those at increased risk from $PM_{2.5}$ exposure), the Administrator still considers it appropriate to ensure that the 24-hour $PM_{2.5}$ standard provides protection against health effects consistently observed in the controlled human exposure studies. He next examines the air quality analyses, described in more detail in section II.A.c.i above, to assess whether during recent air quality conditions, areas meeting the current standards would experience $PM_{2.5}$ concentrations reported in these controlled human exposure studies. He observes that air quality analyses demonstrate that the $PM_{2.5}$ exposures shown to cause consistent effects in the controlled human exposure studies are well above the ambient concentrations typically measured in locations meeting the current primary standards, and therefore suggest that the current primary $PM_{2.5}$ standards provide protection against these ''peak'' concentrations. In fact, at air quality monitoring sites meeting the current primary $PM_{2.5}$ standards (*i.e.,* the 24-hour standard of 35 $\mu g/m^3$ and the annual standard of 12 $\mu g/m^3$), the 2-hour concentrations generally remain below 10 $\mu g/m^3$, and rarely exceed 30 $\mu g/m^3$. Though two-hour concentrations are higher at monitoring sites violating the current standards, they generally remain below 16 $\mu g/m^3$ and rarely exceed 80 $\mu g/m^3$, still below concentrations in CHE studies where consistent effects are observed (*e.g.,* greater than 120 $\mu g/m^3$) (U.S. EPA, 2022b, section 2.3.2.2.3, Figure 2–19, and section 3.3.3.1). Additionally, and in response to public comments, the Administrator notes additional air quality analyses conducted by the EPA,[121] that provide a more refined analysis of whether areas that meet the current standards experience peak concentrations reported in controlled human exposure studies. He notes that 2-hour observations greater than 120 $\mu g/m^3$ and 4-hour observations greater than 38 $\mu g/m^3$ rarely occur (*e.g.,* 0.025% of rolling 2-hour observations are greater than 120 $\mu g/m^3$ and 0.78% of rolling 4-hour observations greater than 38 $\mu g/m^3$). Based on this information, the Administrator finds that the current suite of standards maintains subdaily concentrations of $PM_{2.5}$ in ambient air far below the exposure concentrations in controlled human exposure studies where consistent effects have been observed, and notes that while these studies generally do not include the most at-risk individuals, the exposure concentrations in these studies also do not elicit adverse effects.

Further, in light of the Administrator's emphasis on the annual standard as the controlling standard, with the 24-hour standard providing supplemental protection against peak concentrations, he next considers the potential impact of a revised annual standard of 9.0 $\mu g/m^3$ on the occurrence of peak sub-daily $PM_{2.5}$ concentrations. Specifically, the Administrator takes note of the new air quality analyses [122] where he observes that lower percentages of concentrations greater than 120 $\mu g/m^3$ and 38 $\mu g/m^3$ occur in areas meeting an annual standard of 9.0 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$, versus an annual standard of 12.0 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$. Thus, he concludes that an annual standard that is controlling across most areas of the country will continue to effectively limit peak daily concentrations in conjunction with the existing 24-hour standard, with its level of 35 $\mu g/m^3$ and 98th percentile form, which continues to provide supplemental protection against peak concentrations.

In addition, the Administrator also notes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, support their recommendation to revise the current 24-hour standard by pointing to ''substantial epidemiologic evidence from both morbidity and mortality studies'' which ''includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$'' (Sheppard, 2022a, p. 17 consensus responses). The Administrator notes that the epidemiologic evidence available in this reconsideration, including the studies that restrict short-term $PM_{2.5}$ exposures (*i.e.,* 24-hour $PM_{2.5}$ concentrations) to levels below 25 $\mu g/m^3$, provides support for positive and statistically significant associations between short-term exposure to $PM_{2.5}$ and all-cause mortality (Di et al., 2017a) and CVD hospital admissions (deSouza et al., 2021; Di et al., 2017a). He agrees that these studies help to provide additional support for reaching conclusions on causality in the 2019 ISA. He further agrees that the available epidemiologic studies provide important information that it is appropriate to consider in this reconsideration, including information on associations between health effects and $PM_{2.5}$ exposures in diverse populations that are broadly representative of the U.S. population, and include populations identified as at-risk (*e.g.,* older adults, minority populations), as well as evidence of linear, no-threshold concentration-response relationships in those associations, although with less certainty in the shape of the curve at long-term average concentrations below about 8 $\mu g/m^3$.

However, the Administrator also notes significant limitations in the currently available epidemiologic information that limit his ability to draw conclusions from the key short-term studies, including those that employ restricted analyses, to inform his decision regarding the level of the 24-hour $PM_{2.5}$ standard. As a result of these limitations, the Administrator does not find that the short-term epidemiologic studies, or the other evidence such as the controlled human exposure studies or the risk assessment, provide a sufficient justification for revising the 24-hour standard.

First, he notes that short-term epidemiologic studies examine associations between day-to-day variations in $PM_{2.5}$ concentrations and health outcomes, often over multi-year study periods. As such, these studies report long-term mean 24-hour $PM_{2.5}$ concentrations (*e.g.,* mean 24-hour $PM_{2.5}$ concentrations over multi-year study periods), rather than at specific points in the distribution (*i.e.,* 90th or 98th percentile 24-hour concentrations) at which effects occur. Further, he notes

[121] Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

[122] Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

that while there can be considerable variability in daily exposures over a multi-year study period, the bulk of the observations reflect days with ambient $PM_{2.5}$ concentrations in the middle of the air quality distribution (*i.e.,* ''typical'' days rather than days with extremely low or extremely high concentrations). As a result, the results of these studies are more directly applicable to decisions regarding the annual standard (which is based on the long-term mean of both short- and long-term epidemiologic studies), and the fact that they do not report other air quality statistics, such as the 98th percentile concentrations which might be more directly compared to the level of the 24-hour standard, makes them less useful for informing decisions on the 24-hour standard. As discussed in responding to comments above, the form of the annual standard is based on the annual mean $PM_{2.5}$ concentration averaged over three years,[123] which makes it better suited as a basis for controlling air quality to avoid effects observed in both long-term and short-term epidemiologic studies. By contrast, the form of the 24-hour standard is the 98th percentile averaged over three years, which makes it appropriate for controlling short-term peak concentrations. However, based on the available air quality information, including distribution statistics of $PM_{2.5}$ concentrations and health events reported in the short-term epidemiologic studies, these studies are too limited in their ability to identify health effects attributable to specific short-term peak concentrations that are necessary to evaluate whether the 24-hour standard with its 98th percentile form should be revised (*e.g.,* restricted epidemiologic studies do not report the number or the percentile of health events or the percentile of $PM_{2.5}$ concentrations across the highest part of the restricted air quality distribution, including the 98th percentile). Thus, the Administrator does not consider it appropriate to use the reported means from short-term studies to determine the appropriate level for a 24-hour standard with a 98th percentile form.

Similarly, the Administrator does not consider the results of the restricted analyses to be well suited to informing the choice of level for a 24-hour standard. Restricted analyses use a subset of data from their main analyses to evaluate health events that occur at concentrations below a certain concentration (*e.g.,* 25 $\mu g/m^3$). The Administrator notes that the associations between the health effects (*e.g.,* mortality and cardiovascular morbidity) and $PM_{2.5}$ concentrations remain even after excluding higher concentrations in the restricted analyses, and he also recognizes that the magnitude of the effect is generally greater in the restricted analyses compared to the associations reported in the main analysis. He considers such analyses to be informative in indicating that the health effects association reported in the main (unrestricted) analysis are not driven only by the upper peaks of the $PM_{2.5}$ air quality distribution, but rather persist at lower portions of the distribution (consistent with his emphasis on the annual standard, which is focused on exposures near the mean concentration, where the bulk of the exposure distribution is concentrated). Indeed, he notes that if peak concentrations were the principal driver of health effects associated with $PM_{2.5}$ exposure, one might expect the associations to become weaker as the upper portion of the data is excluded in the restricted analyses, which is not what is reported by the analyses (*e.g.,* the restricted analyses generally report associations that are greater in magnitude compared to the main analyses). However, he disagrees with the assertion by the CASAC in their review of the 2021 draft PA and some public commenters that it would be appropriate to focus on the specific $PM_{2.5}$ concentration (*e.g.,* 25 or 30 $\mu g/m^3$) at which the analysis was restricted as the basis for choosing a 24-hour standard level. The Administrator recognizes that in restricted analyses, while an association continues to persist across the full range of the air quality distribution, and that the cutpoint concentration at which the analysis was restricted (*e.g.,* 25 or 30 $\mu g/m^3$) becomes the maximum $PM_{2.5}$ concentration in the distribution, he also notes that these studies do not provide information related to the distribution of health events and $PM_{2.5}$ concentrations, and as such, he is more uncertain where the bulk of the data are and where he has confidence in the reported association.[124] He notes that no evidence exists to support a conclusion that the $PM_{2.5}$ concentration chosen as the cutpoint in a restricted analysis has any bearing on the concentration at which effects are likely to occur (or not occur). He notes that, as with long-term studies, the evidence does not suggest there is a specific point in the air quality distribution of these short-term studies that represents a ''bright line'' at and above which effects have been observed and below which effects have not been observed. In order to identify a level of the 24-hour standard based on associations between the ''upper end'' of exposures, either in the unrestricted or the restricted analyses, and adverse health effects, it would be necessary to have a better understanding of how specific 24-hour concentrations correspond to the frequency and total number of observed health events in the study. Currently, such information, including 98th percentile statistics, are not reported in the key short-term epidemiologic studies (and if they were reported, the Administrator would have to carefully consider how to weigh the data). As such, in reaching his decision on the primary 24-hour $PM_{2.5}$ standard, the Administrator judges that the currently available information from short-term epidemiologic studies, including those that employ restricted analyses, does not provide a sufficient basis to revise the current 24-hour standard, given that the 24-hour standard focuses on reducing ''peak'' exposures (with its 98th percentile form), but rather that such information supports his judgment that it is appropriate to focus on revising the annual standard for purposes of reducing all exposures, across the entire distribution of air quality, to increase public health protection.

In reaching final decisions regarding the adequacy of the primary 24-hour $PM_{2.5}$ standard, the Administrator continues to view an approach that focuses on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures. Additionally, he emphasizes that improvements in air quality associated with meeting an annual standard level of 9.0 $\mu g/m^3$ will result in lowering risk associated with both long- and short-term $PM_{2.5}$ exposure by lowering the overall air quality distribution. The Administrator concludes that reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in the epidemiologic studies, as the available evidence suggests the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations. However, as in the 2012

[123] The annual mean is calculated by averaging daily values in a calendar quarter and then averaging calendar quarters. See 40 CFR part 50 Appendix N, section 4.4.

[124] These studies do not report information about the distribution of the health events and $PM_{2.5}$ concentrations (*e.g.,* means, medians, other percentiles) in the restricted analyses.

review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term $PM_{2.5}$ exposures in all parts of the country and concludes that, in conjunction with a revised annual standard level of 9.0 μg/m³, it is appropriate to continue to provide supplemental protection by means of a 24-hour standard, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources.

In selecting the level of a 24-hour standard designed to provide supplemental protection against peak exposures (in conjunction with a revised annual standard of 9.0 μg/m³), the Administrator considers the information from the controlled human exposure studies and the EPA's analysis of peak concentrations observed in areas meeting the current standard of 35 μg/m³ in conjunction with a revised standard of 9.0 μg/m³ to be of particular relevance. He notes the controlled human exposure evidence includes studies reporting effects on one or more indicators of cardiovascular function following 2-hour exposures at and above 120 μg/m³, including effects reported at and above 149 μg/m³ for vascular impairment, the effect shown to be most consistent across studies, and less consistent effects at lower concentrations, including a single study at near ambient concentrations (Wyatt et al., 2020) reporting effects following 4-hour exposures at 37.8 μg/m³. He recognizes that the effects observed (in those studies that observed effects) are ones that signal an intermediate effect in the body, likely due to short-term exposure to $PM_{2.5}$, and typically would not, by themselves, be judged as adverse, and the study participants were healthy individuals.

He notes in particular that, in the EPA's analysis, in areas meeting the current 24-hour standard and the revised annual standard 0.029 percent of 2-hour observations and 0.41 percent of 4-hour observations reach $PM_{2.5}$ concentrations higher than 120 μg/m³ and 37.8 μg/m³, respectively. He also notes the lack of evidence of effects from controlled human exposure studies at levels below the current 24-hour standard and the fact that the results of Wyatt et al. (2020) are inconsistent with other available studies, as well as the intermediate nature of effects observed in this study. In his judgment, the small number of occurrences of peak exposures indicate that, in conjunction with a revised annual standard of 9.0 μg/m³, the current 24-hour standard of 35 μg/m³ remains requisite to protect public health with an adequate margin of safety, and that there is substantial basis to doubt whether further improvements in public health would be achieved by further reducing these exposures. Furthermore, the Administrator concludes that due to the limitations and uncertainties outlined above, the information from recent short-term epidemiologic studies, including those that use restricted analyses, is inadequate to inform decisions regarding the adequacy of the current 24-hour standard. Thus, in reaching his decision on the primary 24-hour $PM_{2.5}$ standard, the Administrator concludes that currently available evidence does not call into question the adequacy of the current standard.

In addition to the scientific evidence, the Administrator also considers the risk assessment in evaluating the appropriate level of the 24-hour $PM_{2.5}$ standard. The risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated (*i.e.,* when air quality related to the annual average $PM_{2.5}$ concentrations decrease, daily average $PM_{2.5}$ concentrations are also expected to decrease). When air quality is adjusted to just meet an alternative 24-hour standard level of 30 μg/m³ in the areas where the 24-hour standard is controlling, the risk assessment estimates reductions in $PM_{2.5}$-associated risks across a more limited population and number of areas compared to when air quality is adjusted to simulate alternative levels for the annual standard (*i.e.,* where the annual standard is controlling), and these predictions are largely confined to areas located in the western U.S., several of which are also likely to experience risk reductions upon meeting a revised annual standard. With respect to the CASAC's advice in their review of the 2021 draft PA, the Administrator notes that the minority of CASAC advised that these results suggest that the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations and views these risk assessment results as supporting the conclusion that the current 24-hour standard is adequate (Sheppard, 2022a, p. 4 of consensus letter). In contrast, the majority of CASAC members in their review of the 2021 draft PA, as well as a number of public commenters that support revision of the 24-hour standard, placed greater weight on the evidence-based considerations (*e.g.* scientific evidence, like the restricted analyses) than on the values estimated by the risk assessment, noting the potential for uncertainties in how the risk assessment was able to ''capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective'' (Sheppard, 2022a, p. 4 of consensus letter).

In considering the application of the risk assessment to judgments about the adequacy of the current primary 24-hour $PM_{2.5}$ standard, the Administrator again notes that the risk assessment analyses of $PM_{2.5}$-attributable mortality use input data that include C–R functions from epidemiologic studies that have no threshold and a linear C–R relationship down to zero, as well an air quality adjustment approach that incorporates proportional decreases in $PM_{2.5}$ concentrations to meet lower standard levels. As such, the Administrator notes that this quantitative approach does not incorporate any elements of uncertainty in associations of health effects at lower concentrations and that simulated air quality improvements will always lead to proportional decreases in risk (*i.e.,* each additional μg/m³ reduction produces additional benefits with no clear stopping point at any $PM_{2.5}$ concentration). Therefore, the Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, the results should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. Further, the Administrator notes additionally that air quality analyses have also been considered in looking at the adequacy of the 24-hour standard in controlling peak $PM_{2.5}$ concentrations of potential concern,[125] and that those analyses included monitoring information from across the entire U.S., specifically highlighting areas with higher peak concentrations and including areas impacted by wintertime stagnation and residential wood-burning. Thus, while the risk assessment may have focused on a subset of areas across the U.S. based on the study area selection criteria, the Administrator is considering a broader set of information in reaching his conclusions regarding the appropriateness of the current 24-

[125] Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

hour standard to control peak concentrations.

The Administrator also considers the advice from the CASAC in their reviews of the 2019 draft PA and 2021 draft PA. In their review of the 2019 draft PA, the CASAC ''agrees with the EPA and finds that the available evidence does not call into question the adequacy of public health protection afforded by the current 24-hour $PM_{2.5}$ standard and concurs that it be retained'' (Cox, 2019b, p. 3 of letter). He also notes that in their review of the 2021 draft PA, the CASAC did not reach consensus on whether the current 24-hour standard is adequate, with the majority of the CASAC recommending that the 24-hour standard be revised and the minority of the CASAC recommending that the standard be retained. The majority of the CASAC members further stated that ''[t]here is also less confidence that the annual standard could adequately protect against health effects of short-term exposures. A range of 25–30 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard would be adequately protective'' (Sheppard, 2022a, p. 4 of consensus letter). The Administrator also acknowledges that some public commenters agreed with the majority of the CASAC in supporting a revision to the level of the 24-hour standard to a range between 25–30 $\mu g/m^3$. These commenters cite a number of reasons, including: (1) Results from controlled human exposure studies at near ambient concentrations; (2) aspects of the scientific evidence, including restricted analyses that report positive and significant associations below 35 $\mu g/m^3$; and (3) quantitative risk analyses that show decreasing risk with decreasing $PM_{2.5}$ concentrations. In responding to these comments, the Administrator recognizes that some commenters have different interpretations of the evidence, air quality information, and quantitative results from the risk assessment in this review and would make different judgments about the weight to place on the relative strength and limitations of the currently available scientific evidence and information and how such information could be used in making public health policy decisions on the 24-hour standard. However, as outlined above, the Administrator has carefully considered the information available from controlled human exposure studies and short-term epidemiologic studies, and weighed the strengths and limitations of this evidence in formulating his decisions. Furthermore, as discussed above the Administrator has noted significant uncertainties and limitations inherent in the risk estimates, as well as noting that very few areas were included. In addition, he has given careful consideration to the majority of the CASAC's advice in their review of the 2021 draft PA, but has drawn different conclusions with respect to how currently available evidence and air quality information inform the selection of level for the 24-hour primary $PM_{2.5}$ standard.

In considering the advice of the majority of CASAC, the Administrator notes that a decision to set the level of the 24-hour standard to below 35 $\mu g/m^3$ would place a large amount of emphasis on the potential public health importance of further reducing the occurrence of peak $PM_{2.5}$ concentrations. However, the Administrator concludes that there is insufficient basis to conclude that a more stringent standard to further reduce peak concentrations is needed or would benefit public health. As discussed above, he judges that the $PM_{2.5}$ exposures in controlled human exposure studies that correspond to peak concentrations will already be well controlled via the combination of the revised annual standard, with a level of 9.0 $\mu g/m^3$, and the 24-hour standard with its level 35 $\mu g/m^3$ and its 98th percentile form. Taking into consideration the inconsistent results reported in controlled human exposure studies, the intermediate nature of the health effects observed in the controlled human exposure studies that are not typically considered adverse, the health status of the study participants, and how infrequently peak concentrations of potential concern are anticipated to occur in areas meeting the revised primary annual $PM_{2.5}$ standard, he judges that the current 24-hour standard is requisite to protect against the effects reported in these studies with an adequate margin of safety. Likewise, he judges that neither the epidemiologic studies (including the studies that use restricted analyses) nor the risk assessment provide a sufficient basis for revising the 24-hour standard. As discussed above, the epidemiologic studies, including short-term studies and those with restricted analyses, are not well-suited for identifying a level for a 24-hour standard to address health effects associated with peak concentrations. The restricted analyses support the conclusion that the health effects associated with $PM_{2.5}$ is not associated primarily with exposure to higher concentrations of the main analyses, but like other epidemiologic studies they typically report only long-term mean 24-hour concentrations (*e.g.,* restricted epidemiologic studies do not report the number or the percentile of health events or the percentile of $PM_{2.5}$ concentrations across the highest part of the restricted air quality distribution, including the 98th percentile) and do not identify any particular concentration within the air quality distribution above which effects have been observed and below which effects have not been observed. Similarly, the risk assessment highlights that the annual standard is controlling across much of the U.S. and is generally more effective at reducing risk than the 24-hour standard and, taking into account the limitations and assumptions of the risk assessment discussed above, does not provide a basis for revising the 24-hour standard. For the reasons discussed herein, the Administrator judges that the uncertainties as to whether there would be public health benefits from a more stringent 24-hour standard are too great to justify revising the standard.

Thus, having carefully considered the scientific evidence, quantitative information, CASAC advice, and public comments, the Administrator is retaining the current primary 24-hour $PM_{2.5}$ standard, with its level of to 35 $\mu g/m^3$ and its 98th percentile form. In the Administrator's judgment, based on the currently available evidence and information, a 24-hour standard set at this level and using the specified indicator, averaging time, and form would be requisite to protect public health with an adequate margin of safety, in conjunction with the annual standard. As noted, in evaluating the adequacy of the current standards, the Administrator focuses on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against adverse health effects associated with long- or short-term $PM_{2.5}$ exposures. A 24-hour standard set at a level of 35 $\mu g/m^3$, in conjunction with a revised annual standard level of 9.0 $\mu g/m^3$, in the judgment of the Administrator, provides an appropriate level of public health protection, for both long- and short-term $PM_{2.5}$ exposures. The Administrator believes that a 24-hour standard set at 35 $\mu g/m^3$ would continue to be sufficient to protect public health with a margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection when considered in conjunction with a revised annual standard. The Administrator concludes the current 24-hour standard at a level of 35 $\mu g/m^3$, in conjunction with a revised annual standard level of 9.0 $\mu g/m^3$, will provide appropriate protection

in areas in which the long-term mean concentrations are already relatively low (*i.e.,* below 9 μg/m³) but where there may be elevated short-term peak $PM_{2.5}$ concentrations, often associated with strong local or seasonal sources. This judgment by the Administrator appropriately considers the degree of protection that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In making this decision to retain the current level of the primary $PM_{2.5}$ 24-hour standard at 35 μg/m³ in conjunction with revising the annual standard level from 12.0 μg/m³ to 9.0 μg/m³, given all of the evidence and information discussed above, the Administrator judges that the revised suite of primary $PM_{2.5}$ standards and the rationale supporting these levels appropriately reflects consideration of the strength of the available evidence and other information and its associated uncertainties as well as the advice of CASAC and consideration of public comments. He additionally judges that this suite of primary $PM_{2.5}$ standards is requisite to protect public health, including at-risk populations, with an adequate margin of safety from effects associated with long and short-term exposures to fine particles. This judgment by the Administrator appropriately considers the requirement for standards that are requisite to protect public health but are neither more nor less stringent than necessary.

C. Decisions on the Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the 2019 ISA and ISA Supplement, the scientific and quantitative risk information in the 2022 PA, the advice and recommendations of the CASAC, and public comments, the Administrator revises the current suite of primary $PM_{2.5}$ standards. Specifically, the Administrator revises the level of the primary annual $PM_{2.5}$ standard to 9.0 μg/m³ while retaining its form, indicator and averaging time. In conjunction with revising the primary annual $PM_{2.5}$ standard level to provide protection from effects associated with long- and short-term $PM_{2.5}$ exposures, the Administrator retains the level of 35 μg/m³ and the 98th percentile form, indicator and averaging time of the primary 24-hour $PM_{2.5}$ standard to continue to provide supplemental protection for areas with high peak $PM_{2.5}$ concentrations. The Administrator concludes that this suite of standards is requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures.

III. Rationale for Decisions on the Primary PM_{10} Standard

This section presents the rationale for the Administrator's decision to retain the existing primary PM_{10} standard. This decision is based on a thorough review of the latest scientific information, published through January 2018 [126] and evaluated in the 2019 ISA, on human health effects associated with $PM_{10–2.5}$ in ambient air. As described in section I above and in section 1.2 of the ISA Supplement, the scope of the updated scientific evaluation of the health effects evidence is based on those PM size fractions, exposure durations, and health effects category combinations where the 2019 ISA concluded a causal relationship exists (U.S. EPA, 2019a, U.S. EPA, 2022b).). Therefore, because the 2019 ISA did not conclude a causal relationship for $PM_{10–2.5}$ for any exposure durations or health effect categories, the ISA Supplement does not include an evaluation of additional studies for $PM_{10–2.5}$. As a result, the 2019 ISA continues to serve as the scientific foundation for assessing the adequacy of the primary PM_{10} standard in this reconsideration of the 2020 final decision (U.S. EPA, 2019a, section 1.7; U.S. EPA, 2022a). The Administrator's decision also takes into account the 2022 PA evaluation of the policy-relevant information in the 2019 ISA, CASAC advice and recommendations, and public comments.

In presenting the rationale for the Administrator's final decision and its foundations, Section III.A provides background on the 2020 final decision to retain the primary PM_{10} and a brief summary of key aspects of the currently available health effects information. Section III.B summarizes the CASAC advice and the Administrator's proposed conclusions to retain the existing primary PM_{10} standard, addresses public comments received on the proposal, and presents the Administrator's conclusions on the adequacy of the current standard, drawing on consideration of information in the 2019 ISA and the 2022 PA, advice from the CASAC, and comments from the public. Section III.C summarizes the Administrator's decision on the primary PM_{10} standard.

A. Introduction

The general approach for this reconsideration of the 2020 final decision on the primary PM_{10} standard relies on the scientific information available for this review, as well as the Administrator's judgments regarding the available public health effects evidence, and the appropriate degree of public health protection for the existing standards. With the 2020 decision, the then-Administrator retained the existing primary 24-hour PM_{10} standard, with its level of 150 μg/m³ and its one-expected-exceedance form on average over three years, to continue to provide public health protection against short-term exposures to $PM_{10–2.5}$ (85 FR 82725, December 18, 2020).

1. Background on the Current Standard

Consistent with the 2009 ISA, the 2019 ISA concluded that the available epidemiologic, controlled human exposure, and animal toxicological studies, including uncertainties, provided support for the causality determinations of ''suggestive of, but not sufficient to infer, a causal relationship'' between short-term exposures to $PM_{10–2.5}$ and cardiovascular effects, respiratory effects, and mortality (U.S. EPA, 2019a, section 1.4.2). The 2019 ISA also reached the conclusion that the evidence supports a ''suggestive of, but not sufficient to infer, a causal relationship'' between short-term $PM_{10–2.5}$ exposures and metabolic effects, an endpoint that was not evaluated in the 2009 ISA (U.S. EPA, 2019a, section 1.4.2).

Compared to the 2009 ISA, the 2019 ISA includes expanded evidence for the relationships between long-term exposures and cardiovascular effects, metabolic effects, nervous system effects, cancer, and mortality. The 2019 ISA concluded that the small number of epidemiologic and experimental studies, including uncertainties, contribute to the determination that, ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10–2.5}$ exposure and cardiovascular effects, metabolic effects, nervous system effects, cancer, and mortality and cancer (U.S. EPA, 2019a, p. 10–87). For long-term exposures and cardiovascular effects,

[126] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES–2). References cited in the 2019 ISA, the references considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

cardiovascular effects, and cancer, this is an upgrade from the ''inadequate to infer the presence or absence of a causal relationship'' conclusions in the 2009 ISA (U.S. EPA, 2019a, section 1.4.2). This determination is also the first for long-term exposures and metabolic effects, as the 2009 ISA did not include metabolic effects as an endpoint (U.S. EPA, 2019a section 1.4.2).

In considering the available body of evidence, it was noted in the 2020 review there were considerable uncertainties and limitations associated with the experimental evidence for $PM_{2.5}$ exposures and health effects, and as such more weight was placed on the available epidemiologic evidence. Therefore, the primary focus in the 2020 review was on multi-city and single-city epidemiologic studies that evaluated associations between short-term $PM_{10–2.5}$ and mortality, cardiovascular effects (hospital admissions and emergency department visits, as well as blood pressure and hypertension), and respiratory effects. Despite differences in the approaches [127] used to estimate ambient $PM_{10–2.5}$ concentrations, the majority of the studies reported positive, though often not statistically significant, associations with short-term $PM_{10–2.5}$ exposures. Most $PM_{10–2.5}$ effect estimates remained positive in copollutant models that included either gaseous pollutants or other particulate matter size fractions (*e.g.,* $PM_{2.5}$). In U.S. study locations likely to have met the PM_{10} standard during the study period, a few studies reported positive associations between $PM_{10–2.5}$ and mortality that were statistically significant and remained so in copollutant models (U.S. EPA, 2019a). In addition to the epidemiologic studies, there were a small number of controlled human exposure studies evaluated in the 2019 ISA that reported alterations in heart rate variability or increased pulmonary inflammation following short-term exposure to $PM_{10–2.5}$, providing some support for the associations in the epidemiologic studies. Animal toxicological studies examined the effect of short-term $PM_{10–2.5}$ exposures using non-inhalation (*e.g.,* intratracheal instillation) route.[128] Therefore, these studies provided limited evidence for the biological plausibility of $PM_{10–2.5}$-induced effects (U.S. EPA, 2019a). Although the scientific evidence available in the 2019 ISA expanded the understanding of health effects associated with $PM_{10–2.5}$ exposures, a number of important uncertainties remained. These uncertainties, and their implications for interpreting the scientific evidence, include the following:

- The potential for confounding by copollutants, notably $PM_{2.5}$, was addressed with copollutant models in a relatively small number of $PM_{10–2.5}$ epidemiologic studies (U.S. EPA, 2019a). This was particularly important given the relatively small body of experimental evidence (*i.e.,* controlled human exposure and animal toxicological studies) available to support the independent effect of $PM_{10–2.5}$ on human health. This increases the uncertainty regarding the extent to which $PM_{10–2.5}$ itself, rather than one or more copollutants, is responsible for the mortality and morbidity effects reported in epidemiologic studies.
- There was greater spatial variability in $PM_{10–2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in the potential for increased exposure error for $PM_{10–2.5}$ (U.S. EPA, 2019a). Available measurements did not provide sufficient information to adequately characterize the spatial distribution of $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a). The limitations in estimates of ambient $PM_{10–2.5}$ concentrations ''would tend to increase uncertainty and make it more difficult to detect effects of $PM_{10–2.5}$ in epidemiologic studies'' (U.S. EPA, 2019a).
- Estimation of $PM_{10–2.5}$ concentrations over which reported health outcomes occur remain highly uncertain. When compared with $PM_{2.5}$, there is uncertainty spanning all epidemiologic studies examining associations with $PM_{10–2.5}$ including deficiencies in the existing monitoring networks, the lack of a systematic evaluation of the various methods used to estimate $PM_{10–2.5}$ concentrations and the resulting uncertainty in the spatial as well as the temporal variability in $PM_{10–2.5}$ concentration (U.S. EPA, 2019a).). Given these limitations in routine monitoring, epidemiologic studies employed a number of different approaches for estimating $PM_{10–2.5}$ concentrations, including (1) calculating the difference between PM_{10} and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored PM_{10} and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10–2.5}$ using a dichotomous sampler (U.S. EPA, 2019a, section 1.4.2). Given the relatively small number of $PM_{10–2.5}$ monitoring sites, the relatively large spatial variability in ambient $PM_{10–2.5}$ concentrations, the use of different approaches to estimating ambient $PM_{10–2.5}$ concentrations across epidemiologic studies, and the limitations inherent in such estimates, the distributions of $PM_{10–2.5}$ concentrations over which reported health outcomes occur remain highly uncertain (U.S. EPA, 2019a).

There was relatively little information available to characterize potential exposure differences that may inform the apparent variability in associations between short-term $PM_{10–2.5}$ exposures and health effects across study locations (U.S. EPA, 2019a). Specifically, the potential spatial and temporal variability in $PM_{10–2.5}$ exposures complicates the interpretation of results between study locations as well as the relative lack of information on the chemical and biological composition of $PM_{10–2.5}$ (U.S. EPA, 2009a U.S. EPA, 2019a).

In reaching his decision in 2020 to retain the existing 24-hour primary PM_{10} standard, the then-Administrator specifically noted that, while the health effects evidence was somewhat expanded since the prior reviews, the overall conclusions in the 2019 ISA, including uncertainties and limitations, were generally consistent with what was considered in the 2012 review (85 FR 82725, December 18, 2020). In addition, the then-Administrator recognized that there were still a number of uncertainties and limitations associated with the available evidence.

With regard to the evidence on $PM_{10–2.5}$-related health effects, the then-Administrator noted that epidemiologic studies continued to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10–2.5}$ sources and composition were expected to vary widely. While significant uncertainties remained in the 2020 review, the then-Administrator recognized that this expanded body of evidence had broadened the range of effects that have been linked with $PM_{10–2.5}$ exposures. The studies evaluated in the 2019 ISA expanded the scientific foundation presented in the 2009 ISA and led to revised causality determinations (and new determinations) for long-term $PM_{10–2.5}$

[127] As discussed further below, methods employed by the epidemiologic studies to estimate ambient $PM_{10–2.5}$ concentrations include: (1) Calculating the difference between PM_{10} and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored PM_{10} and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10–2.5}$ using a dichotomous sampler (U.S. EPA, 2019a, section 1.4.2).

[128] Non-inhalation exposure experiments (*i.e.,* intratracheal [IT] instillation) are informative for size fractions (*e.g.,* $PM_{10–2.5}$) that cannot penetrate the airway of a study animal and may provide information relevant to biological plausibility and dosimetry (U.S. EPA, 2019a, section A–12).

exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (85 FR 82726, December 18, 2020). Drawing from his consideration of this evidence, the then-Administrator concluded that the scientific information available since the time of the last review supported a decision to maintain a primary PM_{10} standard to provide public health protection against $PM_{10–2.5}$ exposures, regardless of location, source of origin, or particle composition (85 FR 82726, December 18, 2020). With regard to uncertainties in the available evidence, the then-Administrator first noted that a number of limitations were identified in the 2012 review related to: (1) Estimates of ambient $PM_{10–2.5}$ concentrations used in epidemiologic studies; (2) limited evaluation of copollutant models to address the potential for confounding; and (3) limited experimental studies supporting biological plausibility for $PM_{10–2.5}$-related effects. Despite the expanded body of evidence for $PM_{10–2.5}$ exposures and health effects, the then-Administrator recognized that uncertainties in the 2020 review continued to include those associated with the exposure estimates used in epidemiologic studies, the independence of the $PM_{10–2.5}$ health effect associations, and the biologically plausible pathways for $PM_{10–2.5}$ health effects (85 FR 82726, December 18, 2020). These uncertainties contributed to the 2019 ISA determinations that the evidence is at most ''suggestive of, but not sufficient to infer'' causal relationships (85 FR 82726, December 18, 2020). In considering the available evidence in his basis for the decision, the then-Administrator emphasized evidence supporting ''causal'' and ''likely to be causal'' relationships, and therefore, judged that the $PM_{10–2.5}$-related health effects evidence provided an uncertain scientific foundation for making standard-setting decisions. He further judged limitations in the evidence raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard (85 FR 24126, April 30, 2020). In the 2020 decision, for all of the reasons discussed above and recognizing the CASAC conclusion that the evidence provided support for retaining the current standard, the then-Administrator concluded that it was appropriate to retain the existing primary PM_{10} standard, without revision. His decision was consistent with the CASAC advice related to the primary PM_{10} standard. Specifically, the CASAC agreed with the 2020 PA conclusions that, while these effects are important, the ''evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' and ''supports consideration of retaining the current standard in this review'' (Cox, 2019b, p. 3 of consensus letter). Thus, the then-Administrator concluded that the primary PM_{10} standard (in all of its elements (*i.e.,* indicator, averaging time, form, and level)) was requisite to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10–2.5}$. In light of this conclusion, the EPA retained the existing PM_{10} standard.

2. Overview of the Health Effects Evidence

The information summarized here is based on the scientific assessment of the health effects evidence available in this reconsideration; this evaluation is documented in the 2019 ISA and its policy implications are discussed further in the 2022 PA. As noted above, the ISA Supplement does not include an evaluation of studies for $PM_{10–2.5}$, and the 2019 ISA continues to serve as the scientific foundation for this reconsideration.

a. Nature of Effects

For the health effect categories and exposure duration combinations evaluated, the 2019 ISA concludes that the evidence supports causality determinations for $PM_{10–2.5}$ that are at most ''suggestive of, but not sufficient to infer, a causal relationship''. While the evidence supporting the causal nature of relationships between exposure to $PM_{10–2.5}$ has been strengthened for some health effect categories since the completion of the 2009 ISA, the 2019 ISA concludes that overall ''the uncertainties in the evidence identified in the 2009 ISA have, to date, still not been addressed'' (U.S. EPA, 2019a, section 1.4.2, p. 1–41; U.S. EPA, 2022b, section 4.3.1). Specifically, epidemiologic studies available in the 2012 review relied on various methods to estimate $PM_{10–2.5}$ concentrations, and these methods had not been systematically compared to evaluate spatial and temporal correlations in $PM_{10–2.5}$ concentrations. Methods included: (1) Calculating the difference between PM_{10} and $PM_{2.5}$ concentrations at co-located monitors, (2) calculating the difference between county-wide averages of monitored PM_{10}- and $PM_{2.5}$-based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10–2.5}$ using a dichotomous sampler (U.S. EPA, 2019a, section 1.4.2). As described in the 2019 ISA, there continues to be variability across epidemiologic studies in the approaches used to estimate $PM_{10–2.5}$ concentrations. Additionally, some studies estimate long-term $PM_{10–2.5}$ exposures as the difference between PM_{10} and $PM_{2.5}$ concentrations based on information from spatiotemporal or land use regression (LUR) models, in addition to monitors. The various methods used to estimate $PM_{10–2.5}$ concentrations have not been systematically evaluated (U.S. EPA, 2019a, section 3.3.1.1), contributing to uncertainty regarding the spatial and temporal correlations in $PM_{10–2.5}$ concentrations across methods and in the $PM_{10–2.5}$ exposure estimates used in epidemiologic studies (U.S. EPA, 2019a, section 2.5.1.2.3). Given the greater spatial and temporal variability of $PM_{10–2.5}$ and the lower number of $PM_{10–2.5}$ monitoring sites, compared to $PM_{2.5}$, this uncertainty is particularly important for the coarse size fraction. Beyond the uncertainty associated with $PM_{10–2.5}$ exposure estimates in epidemiologic studies, the limited information on the potential for confounding by copollutants and the limited support available for the biological plausibility of health effects following $PM_{10–2.5}$ exposures also continue to contribute to uncertainty in the $PM_{10–2.5}$ health evidence. Uncertainty related to potential confounding stems from the relatively small number of epidemiologic studies that have evaluated $PM_{10–2.5}$ health effect associations in copollutants models with both gaseous pollutants and other PM size fractions. On the other hand, uncertainty related to the biological plausibility of effects attributed to $PM_{10–2.5}$ exposures results from the small number of controlled human exposure and animal toxicological studies that have evaluated the health effects of experimental $PM_{10–2.5}$ inhalation exposures. The evidence supporting the 2019 ISA's ''suggestive of, but not sufficient to infer, a causal relationship'' causality determinations for $PM_{10–2.5}$, including uncertainties in this evidence, is summarized below in sections III.B.1.a through III.B.1.f.

i. Mortality

Due to the dearth of studies examining the association between long-term $PM_{10–2.5}$ exposure and mortality, the 2009 ISA concluded that the evidence was ''inadequate to determine if a causal relationship exists'' (U.S. EPA, 2009a). As reported in the 2019 ISA, some cohort studies conducted in the U.S. and Europe report positive associations between long-term $PM_{10–2.5}$ exposure and total (nonaccidental)

mortality, though results are inconsistent across studies (U.S. EPA, 2019a, Table 11–11). The examination of copollutant models in these studies remains limited and, when included, $PM_{10–2.5}$ effect estimates are often attenuated after adjusting for $PM_{2.5}$ (U.S. EPA, 2019a, Table 11–11). Across studies, $PM_{10–2.5}$ exposure concentrations are estimated using a variety of approaches, including direct measurements from dichotomous samplers, calculating the difference between PM_{10} and $PM_{2.5}$ concentrations measured at collocated monitors, and calculating difference of area-wide concentrations of PM_{10} and $PM_{2.5}$. As discussed above, temporal and spatial correlations between these approaches have not been evaluated, contributing to uncertainty regarding the potential for exposure measurement error (U.S. EPA, 2019a, section 3.3.1.1 and Table 11–11). The 2019 ISA concludes that this uncertainty ''reduces the confidence in the associations observed across studies'' (U.S. EPA, 2019a, p. 11–125). The 2019 ISA additionally concludes that the evidence for long-term $PM_{10–2.5}$ exposures and cardiovascular effects, respiratory morbidity, and metabolic disease provide limited biological plausibility for $PM_{10–2.5}$-related mortality (U.S. EPA, 2019a, sections 11.4.1 and 11.4). Taken together, the 2019 ISA concludes that, ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between long-term $PM_{10–2.5}$ exposure and total mortality'' (U.S. EPA, 2019a, p. 11–125).

With regard to short-term $PM_{10–2.5}$ exposures and mortality, the 2009 ISA concluded that the evidence is ''suggestive of a causal relationship between short-term exposure to $PM_{10–2.5}$ and mortality'' (U.S. EPA, 2009a). The 2019 ISA included multicity epidemiologic studies conducted primarily in Europe and Asia that continue to provide consistent evidence of positive associations between short-term $PM_{10–2.5}$ exposure and total (nonaccidental) mortality (U.S. EPA, 2019a, Table 11–9). Although these studies contribute to increasing confidence in the $PM_{10–2.5}$-mortality relationship, the use of various approaches to estimate $PM_{10–2.5}$ exposures continues to contribute uncertainty to the associations observed. Recent studies expand the assessment of potential copollutant confounding of the $PM_{10–2.5}$-mortality relationship and provide evidence that $PM_{10–2.5}$ associations generally remain positive in copollutant models, though associations are attenuated in some instances (U.S. EPA, 2019a, section 11.3.4.1, Figure 11–28, Table 11–10). The 2019 ISA concludes that, overall, the assessment of potential copollutant confounding is limited due to the lack of information on the correlation between $PM_{10–2.5}$ and gaseous pollutants and the small number of locations in which copollutant analyses have been conducted. Associations with cause-specific mortality (*i.e.,* cardiovascular and respiratory mortality) provide some support for associations with total (nonaccidental) mortality, though associations with respiratory mortality are more uncertain (*i.e.,* wider confidence intervals) and less consistent (U.S. EPA, 2019a, section 11.3.7). The 2019 ISA concludes that the evidence for $PM_{10–2.5}$-related cardiovascular effects provides only limited support for the biological plausibility of a relationship between short-term $PM_{10–2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019a, section 11.3.7). Based on the overall evidence, the 2019 ISA concludes that, ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between short-term $PM_{10–2.5}$ exposure and total mortality'' (U.S. EPA, 2019a, p. 11–120).

ii. Cardiovascular Effects

In the 2009 ISA, the evidence describing the relationship between long-term exposure to $PM_{10–2.5}$ and cardiovascular effects was characterized as ''inadequate to infer the presence or absence of a causal relationship.'' The limited number of epidemiologic studies reported contradictory results and experimental evidence demonstrating an effect of $PM_{10–2.5}$ on the cardiovascular system was lacking (U.S. EPA, 2019a, section 6.4).

The evidence relating long-term $PM_{10–2.5}$ exposures to cardiovascular mortality remains limited, with no consistent pattern of associations across studies and, as discussed above, uncertainty stemming from the use of various approaches to estimate $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a, Table 6–70). The evidence for associations with cardiovascular morbidity has grown and, while results across studies are not entirely consistent, some epidemiologic studies report positive associations with ischemic heart disease (IHD) and MI (U.S. EPA, 2019a, Figure 6–34); stroke (U.S. EPA, 2019a, Figure 6–35); atherosclerosis (U.S. EPA, 2019a, section 6.4.5); venous thromboembolism (VTE) (U.S. EPA, 2019a, section 6.4.7); and blood pressure and hypertension (U.S. EPA, 2019a, Section 6.4.6). $PM_{10–2.5}$ cardiovascular mortality effect estimates are often attenuated, but remain positive, in copollutants models that adjust for $PM_{2.5}$. For morbidity outcomes, associations are inconsistent in copollutant models that adjust for $PM_{2.5}$, NO_2, and chronic noise pollution (U.S. EPA, 2019a, p. 6–276). The lack of toxicological evidence for long-term $PM_{10–2.5}$ exposures represents a data gap (U.S. EPA, 2019a, section 6.4.10), resulting in the 2019 ISA conclusion that ''evidence from experimental animal studies is of insufficient quantity to establish biological plausibility'' (U.S. EPA, 2019a, p. 6–277). Based largely on the observation of positive associations in some epidemiologic studies, the 2019 ISA concludes that ''evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10–2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2019a, p. 6–277).

With regard to short-term $PM_{10–2.5}$ exposures and cardiovascular effects, the 2009 ISA found that the available evidence for short-term $PM_{10–2.5}$ exposure and cardiovascular effects was ''suggestive of a causal relationship.'' This conclusion was based on several epidemiologic studies reporting associations between short-term $PM_{10–2.5}$ exposure and cardiovascular effects, including IHD hospitalizations, supraventricular ectopy, and changes in heart rate variability (HRV). In addition, dust storm events resulting in high concentrations of crustal material were linked to increases in total cardiovascular disease emergency department visits and hospital admissions. However, the 2009 ISA noted the potential for exposure measurement error primarily due to the different methods used across studies to estimate $PM_{10–2.5}$ concentrations and copollutant confounding in these epidemiologic studies. In addition, there was only limited evidence of cardiovascular effects from a small number of experimental studies (*e.g.* animal toxicological studies and controlled human exposure studies) that examined short-term $PM_{10–2.5}$ exposures (U.S. EPA, 2009a, section 6.2.12.2). In the 2019 ISA, key uncertainties included the potential for exposure measurement error, copollutant confounding, and limited evidence of biological plausibility for cardiovascular effects following inhalation exposure (U.S. EPA, 2019a, section 6.3.13).

The evidence for short-term $PM_{10–2.5}$ exposure and cardiovascular outcomes has expanded since the 2009 ISA, though important uncertainties remain. The 2019 ISA notes that there are a small number of epidemiologic studies reporting positive associations between short-term exposure to $PM_{10–2.5}$ and cardiovascular-related morbidity

outcomes. However, the 2019 ISA notes that there is limited evidence to support that these associations are biologically plausible, or independent of copollutant confounding. The 2019 ISA also concludes that it remains unclear how the approaches used to estimate $PM_{10–2.5}$ concentrations in epidemiologic studies compare amongst one another and subsequently how exposure measurement error varies between each method. Specifically, it is unclear how well-correlated $PM_{10–2.5}$ concentrations are both temporally and spatially across these methods and therefore whether exposure measurement error varies across these methods. Taken together, the 2019 ISA concludes that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10–2.5}$ exposures and cardiovascular effects'' (U.S. EPA, 2019a, p. 6–254).

iii. Respiratory Effects

With regard to short-term $PM_{10–2.5}$ exposures and respiratory effects, the 2009 ISA (U.S. EPA, 2009a) concluded that the relationship between short-term exposure to $PM_{10–2.5}$ and respiratory effects is ''suggestive of a causal relationship'' based on a small number of epidemiologic studies observing associations with some respiratory effects and limited evidence from experimental studies to support biological plausibility. Epidemiologic findings were consistent for respiratory infection and combined respiratory-related diseases, but not for COPD. Studies were characterized by overall uncertainty in the exposure assignment approach and limited information regarding potential copollutant confounding. Controlled human exposure studies of short-term $PM_{10–2.5}$ exposures found no lung function decrements and inconsistent evidence for pulmonary inflammation. Animal toxicological studies were limited to those using non-inhalation (*e.g.,* intratracheal instillation) routes of $PM_{10–2.5}$ exposure.

Recent epidemiologic findings consistently link $PM_{10–2.5}$ exposure to asthma exacerbation and respiratory mortality, with some evidence that associations remain positive (though attenuated in some studies of mortality) in copollutant models that include $PM_{2.5}$ or gaseous pollutants. Epidemiologic studies provide limited evidence for positive associations with other respiratory outcomes, including COPD exacerbation, respiratory infection, and combined respiratory-related diseases (U.S. EPA, 2019a, Table 5–36). As noted above for other endpoints, an uncertainty in these epidemiologic studies is the lack of a systematic evaluation of the various methods used to estimate $PM_{10–2.5}$ concentrations and the resulting uncertainty in the spatial and temporal variability in $PM_{10–2.5}$ concentrations compared to $PM_{2.5}$ (U.S. EPA, 2019a, sections 2.5.1.2.3 and 3.3.1.1). Specifically, the existing monitoring networks do not provide a good characterization of how well correlated concentrations are both spatially and temporally across the $PM_{10–2.5}$ estimation methods and overall spatial and temporal patterns in $PM_{10–2.5}$ concentrations. Taken together, the 2019 ISA concludes that ''the collective evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10–2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019a, p. 5–270).

iv. Cancer

In the 2012 review, little information was available from studies of cancer following inhalation exposures to $PM_{10–2.5}$. Thus, the 2009 ISA determined the evidence was ''inadequate to evaluate the relationship between long-term $PM_{10–2.5}$ exposures and cancer'' (U.S. EPA, 2009a). The scientific information evaluated in the 2019 ISA of long-term $PM_{10–2.5}$ exposure and cancer remains limited, with a few recent epidemiologic studies reporting positive, but imprecise, associations with lung cancer incidence (U.S. EPA, 2019a). Moreover, uncertainty remains in these studies with respect to exposure measurement error due to the use of $PM_{10–2.5}$ predictions that have not been validated by monitored $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a, sections 3.3.2.3 and 10.3.4). Relatively few experimental studies of $PM_{10–2.5}$ have been conducted, though available studies indicate that $PM_{10–2.5}$ exhibits two key characteristics of carcinogens: genotoxicity and oxidative stress. While limited, such experimental studies provide some evidence of biological plausibility for the findings in a small number of epidemiologic studies (U.S. EPA, 2019a, section 10.3.4).

Taken together, the small number of epidemiologic and experimental studies, along with uncertainty with respect to exposure measurement error, contribute to the determination in the 2019 ISA that, ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10–2.5}$ exposure and cancer'' (U.S. EPA, 2019a, p. 10–87).

v. Metabolic Effects

The 2009 ISA did not make a causality determination for $PM_{10–2.5}$-related metabolic effects. One epidemiologic study in the 2019 ISA reports an association between long-term $PM_{10–2.5}$ exposure and incident diabetes, while additional cross-sectional studies report associations with effects on glucose or insulin homeostasis (U.S. EPA, 2019a, section 7.4). As discussed above for other outcomes, uncertainties with the epidemiologic evidence include the potential for copollutant confounding and exposure measurement error due to the different methods used across studies to estimate $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a, Tables 7–14 and 7–15). The evidence base to support the biological plausibility of metabolic effects following $PM_{10–2.5}$ exposures is limited, but a cross-sectional study that investigated biomarkers of insulin resistance and systemic and peripheral inflammation may support a pathway leading to type 2 diabetes (U.S. EPA, 2019a, sections 7.4.1 and 7.4.3). Based on the expanded, though still limited evidence base, the 2019 ISA concludes that, ''[o]verall, the evidence is suggestive of, but not sufficient to infer, a causal relationship between [long]-term $PM_{10–2.5}$ exposure and metabolic effects'' (U.S. EPA, 2019a, p. 7–56).

vi. Nervous System Effects

The 2009 ISA did not make a causality determination for $PM_{10–2.5}$-related nervous system effects. In the 2019 ISA, available epidemiologic studies report associations between $PM_{10–2.5}$ and impaired cognition and anxiety in adults in longitudinal analyses (U.S. EPA, 2019a, Table 8–25, section 8.4.5). Associations of long-term exposure with neurodevelopmental effects are not consistently reported in children (U.S. EPA, 2019a, sections 8.4.4 and 8.4.5). Uncertainties in these studies include the potential for copollutant confounding, as no studies examined copollutants models (U.S. EPA, 2019a, section 8.4.5), and for exposure measurement error, given the use of various methods to estimate $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a, Table 8–25). In addition, there is limited animal toxicological evidence supporting the biological plausibility of nervous system effects (U.S. EPA, 2019a, sections 8.4.1 and 8.4.5). Overall, the 2019 ISA concludes that, ''the evidence is suggestive of, but not sufficient to infer, a causal relationship'' between long-term $PM_{10–2.5}$ exposure and nervous system effects (U.S. EPA, 2019a, p. 8–75).

B. Conclusions on the Primary PM_{10} Standard

In drawing conclusions on the adequacy of the current primary PM_{10} standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the 2020 review and reflects upon the body of information and evidence available in this reconsideration. In so doing, the Administrator has taken into account both evidence-based and quantitative information-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's integrated synthesis of the scientific evidence from animal toxicologic, controlled human exposure, and epidemiologic studies evaluating health effects related to exposures to $PM_{10-2.5}$ as presented in the 2019 ISA and discussed in section III.A.2. In addition to the evidence, the Administrator has weighed a range of policy-relevant considerations as discussed in the 2022 PA and summarized in sections III.B and III.C of the proposal and summarized in section III.B.2 below. These considerations, along with the advice from the CASAC (section III.B.1) and public comments (section III.B.3), are discussed below. A more detailed summary of all significant comments, along with the EPA's responses in the Response to Comments document, can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–00072). This document is available for review in the docket for this rulemaking and through EPA's NAAQS website (link). The Administrator's conclusions in this reconsideration regarding the adequacy of the current primary PM_{10} standard and whether any revisions are appropriate are described in section III.B.4.

1. CASAC Advice

As described in section I.X, the EPA decided to prepare a revised PA for the reconsideration of the 2020 final decision. The CASAC's advice on the 2019 draft PA and the 2021 draft PA was documented in letters to the prior and current Administrators (Cox, 2019b; Sheppard, 2022a) and is summarized below. In reviewing both the 2019 draft PA and the 2021 draft PA, the CASAC agreed with the EPA's preliminary conclusion that the available scientific evidence, including its uncertainties and limitations, does not call into question the adequacy of the current primary PM_{10} standard and that the standard should be retained, without revision.

In its review of the 2019 draft PA, the CASAC concurred with the overall preliminary conclusion that it is appropriate to consider retaining the current primary PM_{10} standard, without revision. In their agreement with the conclusions in the 2019 draft PA, the CASAC stated that ''that key uncertainties identified in the last review remain'' (Cox, 2019b) and that ''none of the identified health outcomes linked to $PM_{10-2.5}$'' were judged to be causal or likely to be causal (Cox, 2019b, p. 12 of consensus responses). Moreover, to reduce these uncertainties in future reviews, the CASAC recommended improvements to $PM_{10-2.5}$ exposure assessment, including a more extensive network for direct monitoring of the $PM_{10-2.5}$ fraction (Cox, 2019b, p. 13 of consensus responses). The CASAC also recommended additional controlled human exposure and animal toxicological studies of the $PM_{10-2.5}$ fraction to improve the understanding of biological mechanisms and pathways (Cox, 2019b, p. 13 of consensus responses). Overall, the CASAC agreed with the EPA's preliminary conclusion in the 2019 draft PA that ''. . . the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that evidence supports consideration of retaining the current standard in this review'' (Cox, 2019b, p. 3 of letter).

In its review of the 2021 draft PA, the CASAC provided advice on the adequacy of the current primary PM_{10} standard in the context of its review of the revised PA for this reconsideration (Sheppard, 2022a) [129].) [130]. In this context, the CASAC supported the preliminary conclusion in the 2021 draft PA that the evidence reviewed in the 2019 ISA does not call into question the public health protection provided by the current primary PM_{10} standard against $PM_{10-2.5}$ exposures and concurs with the 2021 draft PA's overall preliminary conclusion that it is appropriate to consider retaining the current primary PM_{10} standard (Sheppard, 2022a, p. 4 of consensus letter). Additionally, the CASAC concurred that ''. . . at this time, PM_{10} is an appropriate choice as the indicator for $PM_{10-2.5}$'' and ''that it is important to retain the level of protection afforded by the current PM_{10} standard'' (Sheppard, 2022a, p. 4 of consensus letter). The CASAC also recognized uncertainties associated with the scientific evidence, including ''compared to $PM_{2.5}$ studies, the more limited number of epidemiology studies with positive statistically significant findings, and the difficulty in extracting the sole contribution of coarse PM to observed adverse health effects'' (Sheppard, 2022a, p. 19 of consensus responses).

The CASAC recommended several areas for additional research to reduce uncertainties in the $PM_{10-2.5}$ exposure estimates used in the epidemiologic studies, to evaluate the independence of $PM_{10-2.5}$ health effect associations, to evaluate the biological plausibility of $PM_{10-2.5}$-related effects, and to increase the number of studies examining $PM_{10-2.5}$-related health effects in at-risk populations (Sheppard, 2022a, p. 20 of consensus responses). Furthermore, the CASAC ''recognizes a need for, and supports investment in research and deployment of measurement systems to better characterize $PM_{10-2.5}$'' and to ''provide information that can improve public health'' (Sheppard, 2022a, p. 20 of consensus responses).

2. Basis for the Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the 2019 ISA, considerations and staff conclusions and associated rationales presented in the 2020 PA and 2022 PA, and advice and recommendations of the CASAC (88 FR 5634, January 27, 2023). Consistent with previous reviews, the Administrator first considered the available scientific evidence for $PM_{10-2.5}$-related exposures and health effects, as evaluated in the 2019 ISA. As an initial matter, the Administrator recognized that the scientific evidence for $PM_{10-2.5}$-related effects available in this reconsideration is the same body of evidence that was available at the time of the 2020 review, as evaluated in the 2019 ISA and summarized in section III.A.2 above. The 2019 ISA concludes that the evidence supports ''suggestive of, but not sufficient to infer'' causal relationships between short- and long-term exposures to $PM_{10-2.5}$ and cardiovascular effects, cancer, and mortality and long-term $PM_{10-2.5}$ exposures and metabolic effects and nervous system effects (U.S. EPA, 2019a). The Administrator noted that

[129] As described in section I.C.5.b above, the scope of the ISA Supplement did not include consideration of studies of health effects associated with exposure to $PM_{10-2.5}$. Therefore, the information and conclusions presented in the 2022 PA are very similar to those in the 2020 PA.

[130] As described in section I.C.5.b above, the scope of the ISA Supplement did not include consideration of studies of health effects associated with exposure to $PM_{10-2.5}$. Therefore, the information and conclusions presented in the 2022 PA are very similar to those in the 2020 PA.

the evidence for several $PM_{10-2.5}$-related health effects has expanded since the completion of the 2009 ISA, but important uncertainties remain. The uncertainties in the epidemiologic studies contribute to the determinations in the 2019 ISA that the evidence for short and long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019a; U.S. EPA, 2022b, section 4.3.1). Drawing from the evidence evaluated in the 2019 ISA and consideration of the scientific evidence in the 2022 PA, the Administrator noted that, consistent with previous reviews, the 2019 ISA and the 2022 PA highlight a number of uncertainties associated with the evidence, including: (1) $PM_{10-2.5}$ exposure estimates used in epidemiologic studies, (2) independence of $PM_{10-2.5}$ health effect associations, and (3) biological plausibility of the $PM_{10-2.5}$-related effects. These uncertainties contribute to the determinations in the 2019 ISA that the evidence for short-term $PM_{10-2.5}$ exposures and key health effects is ''suggestive of, but not sufficient to infer'' causal relationships. In considering the available scientific evidence, consistent with approaches employed in past NAAQS reviews, the Administrator placed the most weight on evidence supporting ''causal'' and ''likely to be causal'' relationships. In so doing, he noted that the available evidence for short- and long-term $PM_{10-2.5}$ exposures and health effects does not support causality determinations of a ''causal relationship'' or ''likely to be causal relationship.'' Furthermore, the Administrator recognized that, because of the uncertainties and limitations in the evidence base, the 2022 PA does not include a quantitative assessment of $PM_{10-2.5}$ exposures and risk that might further inform decisions regarding the adequacy of the current 24-hour primary PM_{10} standard. Therefore, in light of the 2019 ISA conclusions that the evidence supports ''suggestive of, but not sufficient to infer'' causal relationships. The Administrator judged that there are substantial uncertainties that raise questions regarding the degree to which additional public health improvements would be achieved by revising the existing PM_{10} standard. In considering the available evidence for long-term $PM_{10-2.5}$ exposures, the Administrator noted that there is limited evidence that would support consideration of an annual standard to provide protection against such effects, in conjunction with the current primary 24-hour PM_{10} standard. He preliminarily concluded that the current primary 24-hour $PM_{2.5}$ standard that reduces 24-hour exposures also likely reduces long-term average exposures, and therefore provides some margin of safety against the health effects associated with long-term $PM_{10-2.5}$ exposures.

In reaching his proposed decision on the adequacy of the current primary 24-hour PM_{10} standard, the Administrator also considered advice from the CASAC. As noted above in section III.B.1, the CASAC recognized uncertainties associated with the scientific evidence and agreed with the 2019 draft PA and 2021 draft PA conclusions that the scientific evidence does not call into question the adequacy of the primary PM_{10} standard and supports consideration of retaining the current standard.

When considering the above information together, the Administrator proposed to conclude that the available scientific evidence continues to support a PM_{10} standard to provide some measure of protection against $PM_{10-2.5}$ exposures. Additionally, he recognized that there are important uncertainties and limitations associated with the available evidence for $PM_{10-2.5}$-related health effects, for both short and long-term exposure, as evaluated in the 2019 ISA. Consistent with the decisions in the previous reviews, the Administrator proposed to conclude that these limitations lead to considerable uncertainty regarding the potential public health implications of revising the level of the current primary 24-hour PM_{10} standard. Thus, based on his consideration of the evidence and associated uncertainties and limitations for $PM_{10-2.5}$-related health effects and his consideration of CASAC advice on the primary PM_{10} standard, the Administrator proposed to retain the current primary PM_{10} standard, without revision.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few commenters provided comments on the primary PM_{10} standard. Of those commenters who did provide comments on the primary PM_{10} standard, the majority agree with the EPA's proposed decision to retain the primary PM_{10} standard. In so doing, these commenters agree with the EPA's rationale regarding the available scientific information, including uncertainties and limitations, for informing decisions on the standard. These commenters state that no new scientific evidence or quantitative information has emerged since the 2020 decision to retain the current standard. Furthermore, these commenters note that the EPA did not evaluate any new scientific evidence related to $PM_{10-2.5}$ exposures and health effects as a part of the 2022 ISA Supplement developed for this reconsideration, nor did the revised 2022 PA consider any new or different information from the 2020 PA, and therefore, the EPA reached the same conclusion as is the 2020 PA that the current standard is adequate and should be retained. This group includes industries and industry groups, as well as some State and local governments. All of these commenters generally note their agreements with the rationale provided in the proposal and the CASAC concurrence with the 2021 draft PA conclusion that the available information does not call into question the adequacy of the current standard, and therefore, does not support revision and that the current standard should be retained.

Some commenters, including those from environmental and public health organizations and groups, some states, and individuals, disagreed with the Administrator's proposed decision to retain the current primary PM_{10} standard. These commenters recommend that the EPA revise the primary PM_{10} standard to a lower level to provide increased public health protection, citing to the available scientific evidence, as well as the proposed revision to the primary $PM_{2.5}$ standard.

Commenters who disagreed with the proposal to retain the current standard state that revision to the primary PM_{10} standard is necessary to protect public health with an adequate margin of safety. In their recommendations for revising the standard, some commenters contend that the current standard, with its indicator of PM_{10} to target exposures to $PM_{10-2.5}$, has become less protective as ambient concentrations of $PM_{2.5}$ have been reduced with revisions to that standard. These commenters assert that the current primary PM_{10} standard allows increased exposure to $PM_{10-2.5}$ in ambient air because retaining the primary PM_{10} would allow proportionately more $PM_{10-2.5}$ mass as the $PM_{2.5}$ standard has been revised downward. Moreover, in support of their recommendations, the commenters note that the available evidence of $PM_{10-2.5}$-related health effects has been expanded and strengthened since the time of the last review. Taken together, the commenters contend that the primary PM_{10} standard should be revised and failure to do so would be arbitrary and capricious. Some of these

commenters assert that the level of the primary PM_{10} standard should be revised to 140 or 145 μg/m³, concurrent with a strengthened primary 24-hour $PM_{2.5}$ standard, while other commenters recommend revising the level of the standard to within the range of 65–75 μg/m³, to provide increased public health protection.

We disagree with the commenters that the primary PM_{10} standard should be revised because of reductions in ambient concentrations of $PM_{2.5}$. As an initial matter, we note that overall, ambient concentrations of both PM_{10} and $PM_{2.5}$ have declined significantly over time. Ambient concentrations of PM_{10} have declined by 46% across the U.S. from 2000 to 2019,[131] while $PM_{2.5}$ concentrations in ambient air have declined by 43% during this same time period.[132] As noted in the 2022 PA (p. 2–41), the majority of $PM_{10-2.5}$ sites have generally remained steady and do not exhibit a trend of increasing or decreasing concentrations during this time period, reflecting the relatively consistent level of dust emission across the U.S. from 2000 to 2019 (U.S. EPA, 2022b).

The 2019 ISA provides a comparison of the relative contribution of $PM_{2.5}$ and $PM_{10-2.5}$ to PM_{10} concentrations by region and season using the more comprehensive monitoring data from the NCore network available in this reconsideration (U.S. EPA, 2019, section 2.5.1.1.4). The data indicate that, for urban areas, there are roughly equivalent amounts of $PM_{2.5}$ and $PM_{10-2.5}$ contributing to PM_{10} in ambient air, while rural locations have a slightly higher contribution of $PM_{10-2.5}$ contributing to PM_{10} concentrations than $PM_{2.5}$ (U.S. EPA, 2019, section 2.5.1.1.4, Table 2–7). There is generally a greater contribution from the $PM_{2.5}$ fraction in the East and a greater contribution from the $PM_{10-2.5}$ fraction in the West and Midwest.

The EPA recognizes that when the primary annual $PM_{2.5}$ standard was revised from 15.0 μg/m³ to 12.0 μg/m³ while leaving the 24-hour $PM_{2.5}$ standards unchanged at 35 μg/m³ and the 24-hour PM_{10} standard unchanged at 150 μg/m³, the $PM_{10-2.5}$ fraction of PM_{10} could increase in some areas as the $PM_{2.5}$ fraction decreases (78 FR 3085, March 03, 2013). As described in the 2019 ISA, PM_{10} has become considerably coarser across the U.S. compared to similar observations in the 2009 ISA such that, in urban areas, the mass of the coarse fraction of PM is similar to or greater than the mass of the fine fraction of PM (U.S. EPA, 2019, section 2.5.1.1.4; U.S. EPA, 2009c). However, in considering recent air quality data, the EPA notes that in most areas of the country $PM_{2.5}$ and PM_{10} concentrations have declined and are well below their respective 24-hour standards. While the contribution of fine and coarse PM to PM_{10} mass concentrations may vary spatially and temporally, based on the trends in recent air quality data, the Administrator concludes that the current primary 24-hour PM_{10} standard is maintaining air quality at level that provides requisite protection against $PM_{10-2.5}$. That is, recent air quality data does not suggest that $PM_{10-2.5}$ concentrations have been increasing as $PM_{2.5}$ concentrations have been decreasing. In considering the available $PM_{10-2.5}$ health effects evidence in this reconsideration, there continue to be significant uncertainties and limitations, specifically with respect to the exposure assessment methods used to estimate $PM_{10-2.5}$ concentrations, that make it difficult to fully assess the public health implications of revising the primary PM_{10} standard even considering the possibility for additional variability in the relative ratio of $PM_{2.5}$ to $PM_{10-2.5}$ in current PM_{10} air quality across the U.S. As described in detail above in section III.A.2 and in the proposal (85 FR 5558, January 27, 2023), the uncertainties and limitations in the health effects evidence for $PM_{10-2.5}$ contributed to the determinations in the 2019 ISA that the evidence for key $PM_{10-2.5}$ health effects is ''suggestive of, but not sufficient to infer, a causal relationship'' or ''inadequate to infer the presence, or absence of a causal relationship'' (U.S. EPA, 2019a). While the evidence base for $PM_{10-2.5}$-related health effects has somewhat expanded since the 2009 ISA, the Administrator concludes that the evidence remains too limited to inform judgments regarding whether a more protective primary PM_{10} standard is warranted at this time.

Beyond the uncertainties and limitations associated with the available scientific evidence, the EPA also notes that, while the NCore monitoring network has been expanded since the time of the last review, epidemiologic studies available in this review do not use $PM_{10-2.5}$ NCore data in evaluating associations between $PM_{10-2.5}$ in ambient air and long- or short-term exposures. In the absence of such evidence, the public health implications of changes in ambient $PM_{10-2.5}$ concentrations as $PM_{2.5}$ concentrations decrease remain unclear. Therefore, the EPA continues to recognize this as an area for future research, to address the existing uncertainties (U.S. EPA, 2022b, section 4.6), and inform future reviews of the PM NAAQS. Taken together, as at the time of proposal, the Administrator concludes that these and other limitations in the $PM_{10-2.5}$ evidence raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard, particularly when considering such judgments along with his decision to retain the current primary 24-hour $PM_{2.5}$ standard. Therefore, the EPA does not agree with the commenters that the currently available air quality information or scientific evidence support revisions to the primary PM_{10} standard in this reconsideration.

Consistent with their comments on the 2020 proposal, some commenters disagreed with the Administrator's proposed conclusion to retain the current primary PM_{10} standard, primarily focusing their comments on the need for revisions to the form of the standard or the level of the standard. With regard to comments on the form of the standard, some commenters assert that the EPA should revise the standard by adopting a separate form (or a ''compliance threshold'' in their words)—the 99th percentile, averaged over three years—for the primary PM_{10} standard for continuous monitors, which provide data every day, while maintaining the current form of the standard (one exceedance, averaged over three years) for 1-in-6 samplers, given the increased use of continuous monitoring and to ease the burden of demonstrating exceptional events. These commenters, in support of their comment, contend that the 99th percentile would effectively change the form from the 2nd highest to the 4th highest and would allow no more than three exceedances per year, averaged over three years. These commenters additionally highlight the EPA's decision in the 1997 review to adopt a 99th percentile form, averaged over three years, citing to advantages of a percentile-based form in the Administrator's rationale in that review. The comments further assert that a 99th percentile form for the primary PM_{10} standard is still more conservative than the form for other short-term NAAQS (*e.g.,* $PM_{2.5}$ and NO_2).

[131] PM_{10} concentrations presented as the annual second maximum 24-hour concentration (in μg/m³) at 262 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm10-trends*

[132] $PM_{2.5}$ concentrations presented as the seasonally-weighted annual average concentration (in μg/m³) at 406 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm25-trends*

First, the EPA has long recognized that the form is an integral part of the NAAQS and must be selected together with the other elements (*i.e.,* indicator, averaging time, level) of the NAAQS to ensure the appropriate stringency and requisite degree of public health protection. Thus, if the EPA were to change the form according to the monitoring method it would be establishing two different NAAQS, varying based on the monitoring method. The EPA has not done this to date, did not propose such an approach, and declines to adopt it for the final rule, as we believe such a decision in this final rule is beyond the scope of the proposal, and that each PM standard should have a single form, indicator, level and averaging time, chosen by the Administrator as necessary and appropriate. While certain continuous monitors may be established and approved as a Federal Equivalent Method (FEM) for PM_{10}, as an alternative to a Federal Reference Method (FRM), the use of an FEM is intended as an alternative means of determining compliance with the NAAQS, not as authorizing a different NAAQS.

Even if the commenters had asked that the change in form be made without regard to monitoring method, the EPA does not believe such a change would be warranted. The change in form for continuous monitors suggested by the commenters, without also lowering the level of such a standard, would allow more exceedances and thereby reduce the public health protection provided against exposures to $PM_{10–2.5}$ in ambient air, resulting in a less stringent primary PM_{10} standard than the current standard. These commenters have not provided new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (*i.e.,* 99th percentile), while retaining the other elements of the standard.

With regard to the commenters' assertion that an alternate form of the standard would ease the burden of demonstrating exceptional events, the EPA recognizes, consistent with the CAA, that it may be appropriate to exclude monitoring data influenced by ''exceptional'' events when making certain regulatory determinations. However, the EPA notes that the cost of implementation of the standards may not be considered by the EPA in reviewing the standards. The EPA continues to update and develop documentation and tools to facilitate the implementation of the 2016 Exceptional Events Rule, including new $PM_{2.5}$ implementation focused products under development that are intended to assist air agencies with the development of demonstrations for specific types of exceptional events. With regard to the commenters' specific concerns for wildfires or high winds, the EPA released updated guidance documents on the preparation of exceptional event demonstrations related to wildfires in September 2016, high wind dust events in April 2019, and prescribed fires in August 2019. These guidance documents outline the regulatory requirements and provide examples for air agencies preparing demonstrations for wildfires, high wind dust, and prescribed fire events. For all of the reasons discussed above, the EPA does not agree with the commenters that the form of the primary PM_{10} standard should be revised to a 99th percentile for continuous monitors.

4. Administrator's Conclusions

This section summarizes the Administrator's considerations and conclusions related to the current primary PM_{10} standard. In establishing primary standards under the Act that are ''requisite'' to protect the public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. In so doing, the Administrator notes that his final decision in this reconsideration is a public health policy judgment that draws upon scientific information, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information. Accordingly, he recognizes that his decision requires judgments based on the interpretation of the evidence that neither overstates nor understates the strength or limitations of the evidence nor the appropriate inferences to be drawn. He recognizes, as described in section I.A above, that the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficient but not more stringent than necessary to protect public health, including the health of sensitive groups with an adequate margin of safety.

Given these requirements, and consistent with the primary $PM_{2.5}$ standards discussed above (section II.C.3), the Administrator's final decision in this reconsideration of the current primary PM_{10} standard will be a public health policy judgment that draws upon the scientific information examining the health effects of $PM_{10–2.5}$ exposures, including how to consider the range and magnitude of uncertainties inherent in that information. The Administrator's final decision is based on an interpretation of the scientific evidence that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn.

Having carefully considered advice from the CASAC and public comments, as discussed above, the Administrator notes that the fundamental scientific conclusions on health effects of $PM_{10–2.5}$ in ambient air that were reached in the 2019 ISA and summarized in the 2020 PA and 2022 PA remain valid. Additionally, the Administrator believes the judgments he proposed (85 FR 5558, January 27, 2023) with regard to the evidence remain appropriate. Further, in considering the adequacy of the current primary PM_{10} standard in this reconsideration, the Administrator has carefully considered the policy-relevant evidence and conclusions contained in the 2019 ISA; the rationale and conclusions presented in the 2020 PA and 2022 PA; the advice and recommendations from the CASAC in their reviews of the 2019 draft PA and 2021 draft PA; and public comments, as addressed in section III.B.3 above and in the RTC document. In the discussion below, the Administrator gives weight to the conclusions in the 2020 PA and 2022 PA, with which the CASAC has concurred, as summarized in section III.C of the proposal and takes note of the key aspects of the rationale for those conclusions that contribute to his decision in this review. In considering this information, the Administrator concludes that the preliminary conclusions and policy judgments supporting his proposed decision remain valid, and that the current primary PM_{10} standard provides requisite protection of public health with an adequate margin of safety and should be retained. In considering the 2020 PA and 2022 PA evaluations and conclusions, the Administrator notes that, while the health effects evidence is somewhat expanded since the 2009 ISA as described in section III.A.2 above, the overall conclusions are generally consistent with those reached in the 2009 ISA (U.S. EPA, 2020b, section 4.4). In so doing, he additionally notes that the CASAC supported the preliminary conclusion in the 2019 draft PA and 2021 draft PA that the evidence reviewed in the 2019 ISA does not call into question the public health protection provided by the current primary PM_{10} standard against $PM_{10–2.5}$ exposures and concurs that it is appropriate to consider retaining the current primary PM_{10} standard (Cox,

2019b, p. 13 of consensus responses; Sheppard, 2022a, p. 4 of consensus letter).

As noted below, the scientific evidence for $PM_{10–2.5}$-related health effects has expanded somewhat since the 2012 review, in particular for long-term exposures. The Administrator recognizes, however, that there are a number of uncertainties and limitations associated with the available information, as described in the proposal (85 FR 5558, January 27, 2023) and below. With regard to the current evidence on $PM_{10–2.5}$-related health effects, the Administrator takes note of recent epidemiologic studies that continue to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10–2.5}$ sources and composition are expected to vary widely. While significant uncertainties remain, as described below, the Administrator recognizes that this expanded body of evidence has broadened the range of effects that have been linked with $PM_{10–2.5}$ exposures. These studies provide an important part of the scientific foundation supporting the 2019 ISA's revised causality determinations (and new determinations) for long-term $PM_{10–2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (U.S. EPA, 2019a; U.S. EPA, 2022b, section 4.2). Drawing from his consideration of this evidence, the Administrator concludes that the available scientific information supports a decision to maintain a primary PM_{10} standard to provide public health protection against $PM_{10–2.5}$ exposures, regardless of location, source of origin, or particle composition. With regard to uncertainties in the evidence, the Administrator first notes that a number of limitations were identified in the 2012 review related to: (1) Estimates of ambient $PM_{10–2.5}$ concentrations used in epidemiologic studies; (2) limited evaluation of copollutant models to address the potential for confounding; and (3) limited experimental studies supporting biological plausibility for $PM_{10–2.5}$-related effects. Despite the expanded body of evidence for $PM_{10–2.5}$ exposures and health effects assessed in the 2019 ISA, the Administrator recognizes that uncertainties remain, similar to those in the 2012 review. As summarized in section III.A.2 above and in responding to public comments, uncertainties in the available scientific evidence continue to include those associated with the exposure estimates used in epidemiologic studies, the independence of the $PM_{10–2.5}$ health effect associations, and the biologically plausible pathways for $PM_{10–2.5}$ health effects (U.S. EPA, 2022b, section 4.3). These uncertainties contribute to the 2019 ISA determinations that the evidence is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019a). The Administrator recognizes that the NAAQS must allow for a margin of safety but also places emphasis on evidence supporting ''causal'' or ''likely to be causal'' relationships (as described in sections II.A.2 and III.A.2 above). Finding that there is too much uncertainty that a more stringent standard would improve public health, the Administrator judges that the available evidence provides support for his conclusion that the current standard provides the requisite level of protection from the effects of $PM_{10–2.5}$. In making this judgment, the Administrator considers whether this level of protection is more than what is requisite and whether a less stringent standard would be appropriate to consider. He notes that there continues to be uncertainty associated with the evidence, as reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. The Administrator recognizes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific evidence and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. In light of these considerations and the current body of evidence, including uncertainties and limitations, the Administrator concludes that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety. The Administrator also considers whether the level of protection associated with the current standard is less than what is requisite and whether a more stringent standard would be appropriate to consider. In so doing, the Administrator considers, as discussed above, the level of protection offered from exposures for which public health implications are less clear. In so doing, he again notes the significant uncertainties and limitations that persist in the scientific evidence. In particular, he notes limitations in the approaches used to estimate ambient $PM_{10–2.5}$ concentrations in epidemiologic studies, limited examination of the potential for confounding by co-occurring pollutants, and limited support for the biological plausibility of the serious effects reported in many epidemiologic studies that are reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. Thus, in light of the currently available information, including the uncertainties and limitations of the evidence base available to inform his judgments regarding protection against $PM_{10–2.5}$-related effects, the Administrator does not find it appropriate to increase the stringency of the standard in order to provide the requisite public health protection. Rather, he judges it appropriate to maintain the level of protection provided by the current primary PM_{10} standard for $PM_{10–2.5}$ exposures and he does not judge that the available information and the associated uncertainties indicate the need for a greater level of public health protection.

In reaching his conclusions on the primary PM_{10} standard, the Administrator also considers advice from the CASAC. In their comments, the CASAC noted that uncertainties that were identified in the 2012 review persist in the evidence for $PM_{10–2.5}$-related health effects (Cox, 2019b, p. 13 of consensus responses; Sheppard, 2022a, p. 4 of consensus letter) In considering these comments, the Administrator takes note of the CASAC consideration of the evidence, and associated uncertainties, and its conclusion that the evidence reviewed in the 2019 ISA does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard (Cox, 2019b, p. 3 of letter; Sheppard, 2022a, p. 4 of consensus letter). The Administrator further notes the unanimous conclusions of the CASAC that evidence supports consideration of retaining the current primary PM_{10} standard (Cox, 2019b, p. 3 of consensus letter; Sheppard, 2022a, p. 4 of consensus letter). In addition to the CASAC's advice, the Administrator also considers public comments, the majority of which supported retaining the primary PM_{10} standard, citing to and agreeing with the Administrator's rationale for his proposed decision. The Administrator also recognizes that a few public commenters supported revising the primary PM_{10} standard in order to provide increased protection against $PM_{10–2.5}$-related health effects.

The Administrator also notes that the scientific record for his decision on the primary PM_{10} standard is the same as the record before the then-Administrator in 2020, as the scope of the ISA Supplement focused on health effect categories where the 2019 ISA concluded a causal relationship (*i.e.,*

short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality). Therefore, because no health outcome categories for short- or long-term $PM_{10–2.5}$ exposure in the 2019 ISA were greater than ''suggestive of, but not sufficient to infer, a causal relationship'', the ISA Supplement did not evaluate studies published after the literature cutoff date of the 2019 ISA related to $PM_{10–2.5}$ exposures and health effects. The Administrator further notes his decision is consistent with the decision of the prior Administrator in 2020 to retain the primary PM_{10} standard.

With regard to the indicator for the primary PM_{10} standard, the Administrator recognizes that the 2022 PA notes that the evidence continues to support retaining the PM_{10} indicator to provide public health protection against $PM_{10–2.5}$-related effects. He notes that, consistent with the approaches in previous reviews, a standard with a PM_{10} mass-based indicator, in conjunction with a $PM_{2.5}$ mass-based standard, will result in controlling allowable concentrations of $PM_{10–2.5}$. The Administrator also takes note of the 2019 ISA comparison that showed that the relative contribution of $PM_{2.5}$ and $PM_{10–2.5}$ to PM_{10} concentrations can vary across the U.S. by region and season, with urban locations having a somewhat higher contribution of $PM_{2.5}$ contributing to PM_{10} concentrations than $PM_{10–2.5}$ (U.S. EPA, 2019a, section 2.5.1.1.4, Table 2–7). In these urban locations, where $PM_{2.5}$ concentrations are somewhat higher than in rural locations, the toxicity of the PM_{10} may be higher due to contaminating $PM_{2.5}$. Further, although uncertainties with the evidence persist, the strongest health effects evidence associated with $PM_{10–2.5}$ comes from epidemiologic studies conducted in urban areas. He also notes that the CASAC agreed with the EPA's conclusions that a PM_{10} indicator remained appropriate (Cox, 2019b, p. 13 of consensus responses; Sheppard, 2022a, p. 4 of letter). In light of this information, the Administrator concludes that the PM_{10} indicator remains appropriate and provides protection from exposure to all coarse PM, regardless of location, source of origin, or particle composition.

Similarly, with regard to averaging time, form, and level of the standard, the Administrator takes note of uncertainties in the available evidence and information and continues to find that the current standard, as defined by in all of its elements, is requisite. As an initial matter, the Administrator notes that the current primary PM_{10} standard, with its level of 150 $\mu g/m^3$, 24-hour averaging time, not to be exceeded more than once per year on average over three years, is intended to protect against short-term peak $PM_{10–2.5}$ exposures. In so doing, while the Administrator notes that changes in $PM_{2.5}$ concentrations in ambient air can influence the contribution of the fine and coarse fractions to PM_{10} mass, such that reductions in $PM_{2.5}$ concentrations can lead to more allowable $PM_{10–2.5}$ under the current primary PM_{10} standard, he recognizes that there is no new information available in this reconsideration to suggest that the public health protection provided by the current standard is not requisite or that a more stringent standard is warranted at this time. The Administrator concludes that, particularly in light of his decision to retain the primary 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$ as described in section II.B.4 above, the primary PM_{10} standard would be expected to maintain $PM_{10–2.5}$ concentrations in ambient air below those that have been considered to be associated with serious health effects in past NAAQS reviews. The Administrator also notes that while the scientific evidence available in the 2019 ISA has expanded since the completion of the 2009 ISA, he concludes that this information does not provide support for the causal or likely to be causal relationships upon which he places the greatest weight in considering the adequacy of the current standards. He further concludes that the uncertainties and limitations of the scientific evidence, along with the absence of information to inform a quantitative exposure or risk assessment, make it difficult to reach decisions regarding whether a more protective standard is warranted at this time. He has additionally considered the public comments regarding revisions to these elements of the standard and continues to judge that the existing level and the existing form, in all its aspects, together with the other elements of the existing standard provide an appropriate level of public health protection. For all of the reasons discussed above and recognizing the CASAC's conclusion that the current evidence provides support for retaining the current standard, the Administrator concludes that the current primary PM_{10} standard (in all of its elements) is requisite to protect public health with an adequate margin of safety from effects of $PM_{10–2.5}$ in ambient air and should be retained without revision.

C. Decision on the Primary PM_{10} Standard

For the reasons discussed above and considering information and assessments presented in the 2019 ISA and the 2022 PA, the advice from the CASAC, and public comments, the Administrator concludes that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standard without revision.

IV. Communication of Public Health

A. Air Quality Index Overview

Information about the public health implications of ambient concentrations of criteria pollutants is communicated to the public using the Air Quality Index (AQI) reported on the EPA's AirNow website.[133] The current AQI has been in use since its inception in 1999.[134] It provides useful, timely, and easily understandable information about the daily degree of pollution. The goal of the AQI is to establish a nationally uniform system of indexing pollution concentrations for ozone, carbon monoxide, nitrogen dioxide, PM, and sulfur dioxide. The AQI is recognized internationally as a proven tool to effectively communicate air quality information to the public as demonstrated by the fact that many countries have created similar indices based on the AQI.

The AQI converts an individual pollutant concentration in a community's air to a number on a scale from 0 to 500. Reported AQI values for specific pollutants enable the public to know whether air pollution levels in a particular location are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101–150), unhealthy (151–200), very unhealthy (201–300), or hazardous (301+). Across criteria pollutants, the AQI value of 100 typically corresponds to the level of the short-term (*e.g.,* 24-hour, 8-hour, or 1-hour standard) NAAQS for each pollutant. Below an index value of 100, an intermediate value of 50 is defined either as the level of the annual standard if an annual standard has been established (*e.g.,* $PM_{2.5}$, nitrogen dioxide), a

[133] See *http://www.airnow.gov/.*

[134] In 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies on a voluntary basis (41 FR 37660, September 7, 1976; 52 FR 24634, July 1,1987). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

concentration equal to one-half the value of the 24-hour standard used to define an index value of 100 (*e.g.,* carbon monoxide), or a concentration based directly on health effects evidence (*e.g.,* ozone). An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (*i.e.,* unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous). An AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (*i.e.,* moderate or good). The scientific evidence on pollutant-related health effects for each NAAQS review support decisions related to pollutant concentrations at which to set the various AQI breakpoints, which delineate the AQI categories for each individual pollutant (*i.e.,* the pollutant concentrations corresponding to index values of 150, 200, 300, and 500). The AQI is reported three ways by the EPA and State, local and Tribal agencies, all of which are useful and complementary. The daily AQI is reported for the previous day and used to observe trends in community air quality, the AQI forecast helps people plan their outdoor activities for the next day, and the near-real-time AQI, or NowCast AQI, tells people whether it is a good time for outdoor activity.

Historically, State and local agencies have primarily used the AQI to provide general information to the public about air quality and its relationship to public health. For more than two decades, many State and local agencies, as well as the EPA and other Federal agencies, have been developing new and innovative programs and initiatives to provide more information related to air quality and health messaging to the public in a more timely way. These initiatives, including air quality forecasting, near real-time data reporting through the AirNow website, use of data from air quality sensors on the EPA and U.S. Forest Service's (USFS) Fire and Smoke Map, and air quality action day programs, provide useful, up-to-date, and timely information to the public about air pollution and its health effects. Such information can help the public learn when their well-being may be compromised, so they can take actions to avoid or to reduce exposures to ambient air pollution at concentrations of concern. This information can also encourage the public to take actions that will reduce air pollution on days when concentrations are projected to be of concern to local communities (*e.g.,* air quality action day programs can encourage individuals to drive less or carpool).

B. Air Quality Index Category Breakpoints for $PM_{2.5}$

Recognizing the scientific information available and current AQI reporting practices, the EPA proposed several revisions to the AQI $PM_{2.5}$ breakpoints. EPA solicited and received comments on these proposed revisions. Upon reviewing the information in the proposal and considering the comments received EPA is making final revisions to the AQI category breakpoints for $PM_{2.5}$. This section summarizes the proposed revisions, which can be read in full in the proposal (88 FR 5638, January 27, 2023), significant comments, and final revisions.

1. Summary of Proposed Revisions

One purpose of the AQI is to communicate to the public when air quality is poor and thus when they should consider taking actions to reduce their exposures. The higher the AQI value, the higher the level of air pollution and the greater the health concern. In recognition of the scientific information available that is informing the reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards, including a number of new controlled human exposure and epidemiologic studies published since the completion of the 2009 ISA, as well as additional epidemiologic studies from other peer reviewed documents that evaluate the health effects of wildfire smoke exposure and that can inform the selection of AQI breakpoints at higher $PM_{2.5}$ concentrations,[135] the EPA proposed to make two sets of changes to the $PM_{2.5}$ sub-index of the AQI. First, the EPA proposed to continue to use the approach used in the revisions to the AQI in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100 and 150) to be based on the levels of the primary $PM_{2.5}$ annual and 24-hour standards and proposed to revise the lower breakpoints to be consistent with changes to the primary $PM_{2.5}$ standards that are part of this reconsideration. Second, the EPA proposed to revise the upper AQI breakpoints (200 and above) and to replace the linear-relationship approach used in 1999 to set these breakpoints, with an approach that more fully considers the $PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that have become available in the last 20 years (64 FR 42530, August 4, 1999).

[135] In evaluating the scientific evidence available to inform decisions regarding the AQI breakpoints, the EPA considered studies that were included as a part of the 2019 ISA and ISA Supplement, but also considered other studies that were not included as a part of the review of the air quality criteria. The ISAs have specific criteria for study inclusion and consideration in reaching conclusions regarding causal relationships, and some studies that may not have met those criteria (*e.g.,* epidemiologic studies that evaluate the health effects of wildfire smoke exposure that would have higher $PM_{2.5}$ concentrations, which are outside of the scope of the ISA) were identified as studies that could be used to inform decisions on the AQI, particularly for the upper breakpoints.

a. Air Quality Index Values of 50, 100 and 150

With respect to the lower AQI breakpoints in the proposal (88 FR 5638, January 27, 2023), the EPA proposed to conclude that it is appropriate to continue setting these breakpoints to be consistent with the primary annual and 24-hour $PM_{2.5}$ standard levels. The lowest AQI value of 50 provides the breakpoint between the ''good'' and ''moderate'' categories. At and below this concentration, air quality is considered ''good'' for everyone. Above this concentration, in the ''moderate'' category, the AQI contains advisories for unusually sensitive individuals. The EPA has historically set this breakpoint at the level of the primary annual $PM_{2.5}$ standard. In doing so, the EPA has recognized that: (1) The annual standard is set to provide protection to the public, including at-risk populations, from $PM_{2.5}$ concentrations, which, when experienced on average for a year, have the potential to result in adverse health effects; and (2) the AQI exposure period represents a shorter exposure period (*e.g.,* 24-hour (or less)) while focusing on the most sensitive individuals. The EPA saw no basis for deviating from this approach in this reconsideration. Thus, the EPA proposed to set the AQI value of 50 at a daily (*i.e.,* 24-hour) average concentration equal to the level of the primary annual $PM_{2.5}$ standard that is promulgated.

The historical approach to setting an AQI value of 100, which is the breakpoint between the ''moderate'' and ''unhealthy for sensitive groups'' categories, and above which advisories are generated for sensitive groups, is to set it at the same level as the primary 24-hour $PM_{2.5}$ standard. In so doing, the EPA has recognized that the primary 24-hour $PM_{2.5}$ standard is set to provide protection to the public, including at-risk populations, from short-term exposures to $PM_{2.5}$ concentrations that have the potential to result in adverse health effects. Given this, it is appropriate to generate advisories for sensitive groups at concentrations above this level. In the past, State, local, and Tribal air quality agencies have expressed strong support for this approach (78 FR 3086, January 15, 2013). The EPA saw no basis to deviate

from this approach in this reconsideration. In the proposal (88 FR 5638, January 27, 2023), the EPA proposed to retain the current primary 24-hour $PM_{2.5}$ standard with its level of 35 μg/m³ but took comment on revising the level of that standard to 25 μg/m³ (section II.D.3.b). Thus, the EPA proposed to retain the AQI value of 100 set at the level of the current primary 24-hour $PM_{2.5}$ standard concentration of 35 μg/m³ (*i.e.,* 24-hour average).

With respect to an AQI value of 150, which is the breakpoint between the ''unhealthy for sensitive groups'' and ''unhealthy categories,'' this breakpoint concentration in this reconsideration is based upon the considering the same health effects information, as assessed in the 2019 ISA and ISA Supplement and described in section II above, that informs the proposed decisions on the level of the 24-hour standard and the AQI value of 100. Previously, the Agency has used a proportional adjustment in which the AQI value of 150 was set proportionally to the AQI value of 100. This proportional adjustment inherently recognizes that the available epidemiologic studies provide no evidence of discernible thresholds, below which effects do not occur in either sensitive groups or in the general population, that could inform conclusions regarding concentrations at which to set this breakpoint. Given that the epidemiologic evidence continues to be the most relevant health effects evidence for informing this range of AQI values, the EPA saw no basis to deviate from this approach in this reconsideration. Therefore, the EPA proposed to set an AQI value of 150 proportionally, depending on the breakpoint concentration of the AQI value of 100 (*i.e.,* 55.4 for a 24-hour standard of 35 μg/m³).

b. Air Quality Index Values of 200 and Above

In the proposal (88 FR 5639, January 27, 2023), the EPA summarized the history of setting the AQI values of 300 and above in the 1999 rule (64 FR 42530, August 4, 1999) and established breakpoints for $PM_{2.5}$ in that range. In general, the AQI values between 100 and 500 were based on $PM_{2.5}$ concentrations that generally reflected a linear relationship between increasing index values and increasing $PM_{2.5}$ concentrations.[136] It was found that this linear relationship was generally consistent with the health effects evidence, which suggested that as $PM_{2.5}$ concentrations increase, increasingly larger numbers of people are likely to experience serious health effects in this range of $PM_{2.5}$ concentrations (64 FR 42536, August 4, 1999). For the AQI breakpoint of 500, the concentration was based on the method used to establish a previously existing PM_{10} breakpoint that was informed by studies conducted in London using the British Smoke method, which uses a different particle size cutpoint as noted in the proposal (88 FR 5639, January 27, 2023). Due to limited ambient $PM_{2.5}$ monitoring data available at that time, the decision on the 500 value concentration for $PM_{2.5}$ was based on the stated assumption that PM concentrations measured by the British Smoke method were approximately equivalent to $PM_{2.5}$ concentrations (64 FR 42530, August 4, 1999). Given that the British Smoke method has a larger particle size cutpoint than the current $PM_{2.5}$ monitoring method, which has a cutpoint of 2.5 microns, a concentration of 500 μg/m³ based on the British Smoke method would be equivalent to a lower $PM_{2.5}$ concentration. With respect to the upper breakpoints of the AQI, the EPA has historically been concerned about establishing these upper breakpoints using evidence based on larger size fractions of PM, given that $PM_{2.5}$ is the indicator for the AQI. While monitoring data for higher $PM_{2.5}$ concentrations in ambient air has been available for many years, the health effects evidence has only recently become available for consideration in informing decisions on the upper breakpoints of the AQI.

As part of this reconsideration, the EPA recognized that the health effects evidence associated with $PM_{2.5}$ exposure has greatly expanded in recent years. Multiple controlled human exposure studies have become available that provide information about health effects across a range of concentrations. While many of the new studies evaluated in the 2019 ISA focused on examining health effects associated with exposure to lower $PM_{2.5}$ concentrations, there are also several new controlled human exposure studies that provide information about the health effects observed in study participants at concentrations well above the standard levels. Additionally, there are also epidemiologic studies now available and evaluated in other Agency peer-reviewed documents that can inform health effects associated with higher $PM_{2.5}$ concentrations (U.S. EPA, 2021b).[137] Thus, the EPA concluded that it is appropriate to reevaluate the upper AQI breakpoints, taking into account the expanded body of scientific evidence, particularly given several new epidemiologic studies conducted during high pollution events like wildfires and multiple controlled human exposure studies. While it remains unclear the exact $PM_{2.5}$ concentrations at which specific health effects occur, the more recent studies do provide more refined information about the concentration range in which these effects might occur in some populations. These studies provide support for coherence of effects across scientific disciplines and potentially biologically plausible pathways for the overt population-level health effects observed in epidemiologic studies. Therefore, taking into account the short exposure time period in these studies (*e.g.,* 1–6 hours) and that the studies generally do not include at-risk (or sensitive) populations, but rather young, healthy adults, these studies, in conjunction with information from epidemiologic studies, the EPA preliminarily concluded it would be appropriate to be more cautionary and offer advisories to the public for reducing exposures at lower concentrations than recommended with the current AQI breakpoints.

The AQI value of 200 is the breakpoint between the ''unhealthy'' and ''very unhealthy'' categories. At AQI values above 200, the AQI would be providing a health warning that the risk of anyone experiencing a health effect following short-term exposures to these $PM_{2.5}$ concentrations has increased. To inform proposed decisions on this breakpoint, the EPA takes note of studies indicating the potential for respiratory or cardiovascular effects that are on their own representative of or are on the biologically plausible pathway to more serious health outcomes (*e.g.,* emergency department visits, hospital admissions). The controlled human exposure studies evaluated in the 2009 and 2019 ISAs provide evidence of inflammation as well as cardiovascular effects in healthy subjects at and above 120 μg/m³. For example, Ramanathan et al. (2016) observed a transient reduction in antioxidant/anti-inflammatory function after exposing healthy young subjects to a mean concentration of 150 μg/m³ of $PM_{2.5}$ for 2 hours. Urch et al.

[136] The AQI breakpoint at 150 was originally set in 1999 to be linearly related to the concentrations at the 100 and 500 breakpoints but then revised in 2012 to be proportional to the AQI breakpoint concentration at 100 (78 FR 3181, January 15, 2013).

[137] In this reconsideration, the controlled human exposure studies were evaluated in the 2019 ISA, whereas the epidemiologic studies of wildfire smoke exposures were included in the EPA Comparative Assessment of the Impacts of Prescribed Fire Versus Wildfire (CAIF): A Case Study in the Western U.S. (U.S. EPA 2021b).

(2010) also reported increased markers of inflammation when exposing both asthmatic and non-asthmatic subjects to a mean concentration of 140 μg/m^3 of $PM_{2.5}$ for 3 hours. In studies specifically examining cardiovascular effects, Ghio et al. (2000) and Ghio et al. (2003) exposed healthy subjects to a mean concentration of 120 μg/m^3 for 2 hours and reported significantly increased levels of fibrinogen, a marker of coagulation that increases during inflammation. Sivagangabalan et al. (2011) exposed healthy subjects to a mean concentration of 150 μg/m^3 of $PM_{2.5}$ for 2 hours and noted an increased QT interval (3.4 ± 1.4) indicating some evidence for conduction abnormalities, an indicator of possible arrhythmias. Lastly, Brook et al. (2009) reported a transient increase of 2.9 mm Hg in diastolic blood pressure in healthy subjects during the 2-hour exposure to a mean concentration of 148 μg/m^3 of $PM_{2.5}$.

In addition to epidemiologic studies evaluated in the 2019 ISA that analyzed exposures at ambient $PM_{2.5}$ concentrations, there are a number of recent epidemiologic studies focusing on wildfire smoke that have become available that were evaluated in the EPA's recently released peer-reviewed assessment on wildland fire (U.S. EPA, 2021b). One of these studies, Hutchinson et al. (2018), conducted a bidirectional case-crossover analysis to examine associations between wildfire-specific $PM_{2.5}$ exposure and respiratory-related healthcare encounters (*i.e.,* ED visits, inpatient hospital admissions, and outpatient visits) prior and during the 2007 San Diego wildfires. This study found positive and significant associations to $PM_{2.5}$ exposures and respiratory-related healthcare encounters. Further, during the initial 5-day period of the wildfire event, the study observed that there was evidence of increases in a number of respiratory-related outcomes particularly ED visits for asthma, upper respiratory infection, respiratory symptoms, acute bronchitis, and all respiratory-related visits (Hutchinson et al., 2018). When examining the air quality during the wildfire event, $PM_{2.5}$ concentrations were highest during the initial five days of the wildfire, with 24-hour average $PM_{2.5}$ concentrations of 89.1 μg/m^3 across all zip codes and with the highest 24-hour average of 160 μg/m^3 on the first day (Hutchinson et al., 2018).

When considering this collective body of evidence from controlled human exposure and epidemiologic studies, the Agency proposed to set an AQI value of 200 at a daily (*i.e.,* 24-hour average) concentration of $PM_{2.5}$ of 125 μg/m^3. As discussed above and in the proposal (88 FR 5640, January 27, 2023), this concentration is at the lower end of the concentrations consistently shown to be associated with respiratory and cardiovascular effects in controlled human exposure studies following short-term exposures (*e.g.,* 2–3 hours) and in young, healthy adults (Ghio et al., 2000; Ghio et al., 2003; Urch et al., 2010; Ramanathan et al., 2016; Sivagangabalan et al., 2011; and Brook et al., 2009) and also within the range of 5-day average and maximum concentrations observed to be associated with respiratory-related outcomes following exposure to wildfire smoke (Hutchinson et al., 2018).

The AQI value of 300 denotes the breakpoint between the ''very unhealthy'' and ''hazardous'' categories, and thus marks the beginning of the ''hazardous'' AQI category. At AQI values above 300, the AQI provides a health warning that everyone is likely to experience effects following short-term exposures to these $PM_{2.5}$ concentrations. To inform decisions on this AQI breakpoint, the EPA takes note of controlled human exposure studies that consistently show subclinical effects which are often associated with more severe cardiovascular outcomes. As discussed above, Brook et al. (2009) reported a transient increase of 2.9 mm Hg in diastolic blood pressure in healthy subjects during the 2-hour exposure to a mean concentration of 148 μg/m^3 of $PM_{2.5}$. Bellavia et al. (2013) exposed healthy subjects to an average $PM_{2.5}$ concentration of 242 μg/m^3 for 2 hours and reported increased systolic blood pressure (2.53 mm Hg). Tong et al. (2015) exposed healthy subjects to an average $PM_{2.5}$ concentration of 253 μg/m^3 for 2 hours and observed a significant increase in diastolic blood pressure (2.1 mm Hg) and a nonsignificant increase in systolic blood pressure (2.5 mm Hg). Lucking et al. (2011) reported impaired vascular function and increased potential for coagulation when exposing healthy subjects to diesel exhaust (DE) with an average $PM_{2.5}$ concentration of 320 μg/m^3 for a duration of 1 hour.[138] These studies all provided evidence of impaired vascular function, including vasodilatation impairment and increased thrombus formation, with Tong et al. (2015), Bellavia et al. (2013), Brook et al. (2009) all reporting increases in blood pressure. Additionally, Behbod et al. (2013) reported increased inflammatory markers following a 2-hour exposure to an average $PM_{2.5}$ concentration of 250 μg/m^3 in healthy subjects.

In addition to the controlled human exposure studies discussed above, the epidemiologic study conducted by DeFlorio-Barker et al. (2019) examined the relationship between wildfire smoke and cardiopulmonary hospitalizations among adults 65 years of age and older from 2008–2010 in 692 U.S. counties. The authors reported a 2.22% increase in all-cause respiratory hospitalizations on wildfire smoke days for a 10 μg/m^3 increase in 24-hour average $PM_{2.5}$ concentrations (DeFlorio-Barker et al., 2019). The maximum 24-hour average concentration in this study on wildfire smoke days was 212.5 μg/m^3 (DeFlorio-Barker et al., 2019). In considering this study, the EPA notes the increased probability that even healthy adults experience effects at this maximum exposure concentration, particularly given that this maximum concentration is near the exposure concentrations in controlled human exposure studies that consistently reported evidence of impaired vascular function and several that reported increases in blood pressure in healthy adults following 2-hour exposures.

Based on the information discussed above and in the proposal (88 FR 5640, January 27, 2023), the EPA proposed to revise the 300 level of the AQI, which marks the beginning of the ''hazardous'' AQI category, to a concentration that is consistent with the $PM_{2.5}$ concentrations associated with health effects as reported in the controlled human exposure (Brook et al., 2009; Bellavia et al., 2013; Tong et al., 2015; Behbod et al., 2013) and epidemiologic studies (DeFlorio-Barker et al. (2019). Specifically, the Agency proposed to set an AQI value of 300 at a daily (*i.e.,* 24-hour average) $PM_{2.5}$ concentration of 225 μg/m^3. This concentration falls between the 2-hour average concentrations reported in controlled human exposure studies found to be consistently associated, in healthy adults, with impaired vascular function and/or increases in blood pressure, which could both be a precursor to more severe cardiovascular effects following short-term (1- to 2-hour) exposures, and the maximum 24-hour average $PM_{2.5}$ concentrations on wildfire smoke days reported in the epidemiologic study conducted by DeFlorio-Barker et al. (2019).

[138] Although participants in Lucking et al. (2011) were exposed to diesel exhaust (DE), the authors also conducted analyses using a particle trap, and as noted in the 2019 ISA, this type of study design allows for the assessment of the role of $PM_{2.5}$ on the health effects observed by removing PM from the DE mixture.

c. Air Quality Index Value of 500

Lastly, the EPA also proposed revisions to the 500 value of the AQI. The 500 value of the AQI is within the ''hazardous'' category but is specified and used to calculate the slope of the AQI values in the ''hazardous category'' above and below AQI values of 500. In the past, this breakpoint had a very prominent role in determining the current upper AQI values given that it was used as part of the linear relationship with the concentration at the AQI value of 100 to determine the AQI values of 200 and 300 in 1999 (64 FR 42530, August 4, 1999).

As discussed above and in the proposal (88 FR 5641, January 27, 2023), the current breakpoint concentration for the 500 value of the AQI was set in 1999 at a 24-hour average $PM_{2.5}$ concentration of 500 μg/m³ and was based on studies conducted in London using the British Smoke method, which used a different particle size cutpoint and likely overestimated the $PM_{2.5}$ concentration. In looking to improve upon that approach, the EPA considered several recent controlled human exposure studies that observe health effects that are on the biologically plausible pathway to more severe cardiovascular outcomes and note that these seem to follow exposures to high $PM_{2.5}$ concentrations that are well above those typically observed in ambient air. More specifically, in controlled human exposure studies, Vieira et al. (2016a) and Vieira et al. (2016b) exposed healthy subjects and subjects with heart failure to diesel exhaust (DE) with a mean $PM_{2.5}$ concentration of 325 μg/m³ for 21 minutes and reported decreased stroke volume, and increased arterial stiffness (an indicator of endothelial dysfunction) in both healthy and heart failure subjects.[139] Also as summarized above and discussed in the proposal (88 FR 5641, January 27, 2023), Lucking et al. (2011) exposed healthy subjects to DE with a mean $PM_{2.5}$ concentration of 320 μg/m³ for 1 hour.[140] Epidemiologic studies have linked the types of cardiovascular effects observed in these controlled human exposure studies with the exacerbation of ischemic heart disease (IHD) and heart failure as well as myocardial infarction (MI) and stroke.

In addition to the controlled human exposure studies discussed in the proposal (88 FR 5641, January 27, 2023) and summarized above, recent epidemiologic studies examining the relationship between concentrations of $PM_{2.5}$ during wildfires and respiratory health also informed the proposed decisions on the concentration for the AQI value of 500. As discussed in the proposal (88 FR 5641, January 27, 2023) and summarized earlier in this section, Hutchinson et al. (2018) reported increases in a number of respiratory-related ED visits for asthma, upper respiratory infection, respiratory symptoms, acute bronchitis, and all combined respiratory-related visits based on data from Medi-Cal claims for emergency department presentations, inpatient hospitalizations, and outpatient visits during the initial 5-day period of the 2007 San Diego fire. During the initial 5-day window, $PM_{2.5}$ concentrations were found to be at their highest with the 95th percentile of 24-hour average concentrations of 333 μg/m³.

Although studies of short-term (*i.e.,* daily) exposures to wildfire smoke are more informative in considering alternative level for the AQI value of 500 since they mirror the 24-hour exposure timeframe, additional information from epidemiologic studies of longer-term exposures (*i.e.,* over many weeks) during wildfire events can provide supporting information. As discussed in the proposal (88 FR 5641, January 27, 2023) and summarized here, Orr et al. (2020) conducted a longitudinal study that reported exposure to wildfire smoke from a multi-month fire resulted in reduced lung function in subsequent years and concluded that exposure to high $PM_{2.5}$ concentrations during a multi-week fire event may lead to health consequences, such as declines in lung function. During the 2017 wildfire event (August 1 to September 19, 2017), Orr et al. (2020) reported that many days during the multi-month fire had $PM_{2.5}$ concentrations above 300 μg/m³, resulting in a daily average $PM_{2.5}$ concentration of 220.9 μg/m³ with a maximum $PM_{2.5}$ concentration of 638 μg/m³.

The controlled human exposure studies provide biological plausibility for results of epidemiologic studies that document increases in respiratory-related health care events during the wildfires. The collective evidence from controlled human exposure and epidemiologic studies, which includes decreases in stroke volume, increased arterial stiffness, impaired vascular function and respiratory-related healthcare encounters provide health-based evidence that informed the proposed decisions on the level of the AQI value of 500. Given the concentrations observed in these studies, the Agency proposed to revise the AQI value of 500 to a level set at a daily (*i.e.,* 24-hour average) $PM_{2.5}$ concentration of 325 μg/m³. This concentration is at or below the lowest concentrations observed in the controlled human exposure studies associated with more severe effects discussed above and also at the low end of the daily concentrations observed in the epidemiologic studies conducted by Hutchinson et al. (2018) and Orr et al. (2020).

Table 1 below summarizes the proposed breakpoints for the $PM_{2.5}$ sub-index.

TABLE 1—PROPOSED BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX

AQI category	Index values	Proposed breakpoints (μg/m³, 24-hour average)
Good	0–50	0.0–(9.0–10.0)
Moderate	51–100	(9.1–10.1)–35.4
Unhealthy for Sensitive Groups	101–150	35.5–55.4
Unhealthy	151–200	55.5–125.4
Very Unhealthy	201–300	125.5–225.4

[139] These effects were attenuated when the DE was filtered, to reduce $PM_{2.5}$ concentrations, indicating the effects were likely associated with $PM_{2.5}$ exposure.

[140] When applying a particle trap, $PM_{2.5}$ concentrations were reduced, and effects associated with cardiovascular function including impaired vascular function, as measured by vasodilatation and thrombus formation were attenuated indicating associations with $PM_{2.5}$.

TABLE 1—PROPOSED BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX—Continued

AQI category	Index values	Proposed breakpoints ($\mu g/m^3$, 24-hour average)
Hazardous [1]	301+	225.5

[1] AQI values between breakpoints are calculated using equation 1 in appendix G. For AQI values in the hazardous category, AQI values greater than 500 should be calculated using equation 1 and the $PM_{2.5}$ concentration specified for the AQI value of 500.

2. Summary of Significant Comments on Proposed Revisions

The EPA received many comments on the proposed changes to the $PM_{2.5}$ AQI breakpoints. Many commenters generally supported all the proposed revisions to the AQI breakpoints based on the revisions to the primary annual and daily $PM_{2.5}$ standards and recent scientific evidence discussed in the proposal (88 FR 5558, January 27, 2023). However, we received specific comments on proposed revisions to the breakpoints in the lower end of the AQI, related to their linkage to the annual and daily $PM_{2.5}$ standards, and proposed revisions to the breakpoints at the upper end of the AQI, based on EPA's interpretation of available health effects evidence.

a. Air Quality Index Values of 50, 100, and 150

Some commenters agreed with using the historical approach of setting the 50, 100 and 150 breakpoints of the AQI to be consistent with the primary $PM_{2.5}$ standards. Some cited the reason that this approach creates consistent communication with respect to air quality and the standards, and this is how the other AQI sub-indices are set. A few commenters disagreed with the historical approach and suggested instead that the 50 breakpoint of the AQI should not be revised at all, or that the 50 and 100 breakpoints of the AQI should be supported directly by health data similar to the basis for the proposed 200, 300 and 500 breakpoints.

The few commenters that disagreed with the historical approach of the 50 breakpoint of the AQI noted that setting a short-term breakpoint to annual standard was not logical since it is a long-term standard and not meant to be interpreted for short-term messaging with the AQI, in particular when reported hourly via the NowCast. These commenters also noted that additional studies are needed to identify the health impacts of short-term exposures at low concentrations. They also noted that lowering the 50 breakpoint of the AQI in conjunction with the annual standard may cause confusion with the public because some State programs and policy decisions are connected to the AQI while others are based on PM concentrations, which could lead to inconsistent messaging reducing the public's trust. These comments were supported by noting that revised breakpoints could lead to more moderate days than in the past, but the monitor values would be the same as before when the commenters considered it ''healthy,'' possibly eroding trust in air agencies' messaging. Commenters also noted if the breakpoints are revised, the public will not visually be able to detect the difference between what was considered a good AQI day versus a now moderate AQI day.

The EPA disagrees with these commenters. With respect to setting a short-term breakpoint to the level of a much longer-term (annual) standard, setting the lower AQI breakpoints at the level of the annual and daily $PM_{2.5}$ standards for communication purposes was discussed in the proposed reconsideration (88 FR 5558, January 27, 2023) and previously supported by State organizations in the 2012 PM Final Rule (77 FR 38890, June 29, 2012). Both the AQI and the Pollutant Standards Index, which came before it, have historically been normalized across pollutants by defining an index value of 50 and 100 as the numerical level of the annual (when defined) and short-term (*i.e.,* averaging time of 24-hours or less) primary NAAQS for each pollutant. This approach clearly communicates the air quality to the public. The EPA considers this approach to be appropriate given the available evidence and structure of the standard. As discussed in section II.B above and in the notice of final rulemaking for the 2012 review (77 FR 38890, June 29, 2012), the primary annual and 24-hour $PM_{2.5}$ standards work together in concert to provide public health protection. The annual $PM_{2.5}$ standard is generally viewed as the principal means of providing public health protection against ''typical'' daily and annual $PM_{2.5}$ exposures, while the 24-hour $PM_{2.5}$ standard is generally viewed as a means of providing protection against short-term exposures to ''peak'' $PM_{2.5}$ concentrations, such as can occur in areas with strong contributions from local or seasonal sources, even when annual average $PM_{2.5}$ concentrations remain relatively low. Because the annual standard provides public health protection for typical daily $PM_{2.5}$ exposures, the EPA thinks it is appropriate to use that level for the 50 breakpoint of the AQI and describe daily air quality at and below the level of the annual standard ''Good.'' Since an annual standard allows for days with air quality above that level, it is appropriate to call days just above it ''Moderate.'' If the 50 breakpoint of the AQI was set at a level above the annual standard, it would be possible for the majority of days to be called ''good'' in a year when an area exceeds the annual standard. This could cause confusion with the public about air quality if the general perception is that local air quality is ''good,'' but the area fails to meet the annual standard. In addition, the EPA continues to find it appropriate to use the NowCast with the $PM_{2.5}$ AQI index to provide more real-time information to the public. As discussed in the AQI Technical Assistance Document, while the NowCast algorithm is approximating a 24-hour average exposure, it can reflect concentrations observed over shorter averaging times when air quality is changing rapidly (U.S. EPA, 2018a). The EPA continues to consider the use of the primary annual standard level suitable in the NowCast given the health evidence supporting the standard and given that the reported concentrations are an approximation of ''typical'' daily exposure. Additionally, the EPA reflects the nature of the NowCast in the associated health messaging.

With regard to the commenter stating the public may not be able to visually detect a difference in the air quality, the EPA notes that the AQI is intended to be a communication tool for public awareness precisely because it is generally difficult for the public to visually judge air quality risks when air pollution is ''moderate.'' Moreover, since the establishment of the AQI, the EPA and State and local air agencies and organizations have developed experience in educating the public about changes in the standards and,

concurrently, related changes to AQI breakpoints and advisories. When the standards change, the EPA and State and local agencies have sought to help the public understand that air quality is not getting worse, it's that the health evidence underlying the standards and the AQI has changed. The EPA's Air Quality System (AQS), the primary repository for air quality monitoring data, is also adjusted to reflect the revised breakpoints. Specifically, all historical AQI values in AQS are recomputed with the revised breakpoints, so that all data queries and reports downstream of AQS will show appropriate trends in AQI values over time. If any State, local or Tribal air agency is concerned that people are or will be confused on a moderate AQI day, then they could use the communication information that has been developed with this rulemaking.

Some commenters stated that the AQI should not necessarily be linked to the primary $PM_{2.5}$ standards. One example is the comment that if the annual standard is not lowered to 8 μg/m³, the EPA should lower the 50 breakpoint of the AQI to that level to better inform the public of the need for behavioral modifications to reduce the harm to health from $PM_{2.5}$ exposure. Similar to the reasons discussed above, the EPA concludes that setting the 50 breakpoint of the AQI at the level of the annual $PM_{2.5}$ standard is appropriate from a health perspective and for communication purposes. The Administrator has judged the primary annual standard (in conjunction with the other primary standards) as revised in this final action to be requisite to protect public health with an adequate margin of safety, based on the health evidence discussed in section II.A.2. Setting the 50 breakpoint lower than the annual standard also has the potential to cause confusion with the public since it does not reflect the standards and the Administrator's judgments about the standards as well.

With regard to the 100 breakpoint of the AQI, several commenters expressed the view that the level of the 24-hour $PM_{2.5}$ standard and an AQI value of 100 should be set at 25 μg/m³ based on the body of evidence and lower end of the range recommended by CASAC. These commenters noted that if the current 24-hour standard and AQI value of 100 is retained at 35 μg/m³ then the public will not be able to make informed decisions about actions to take to protect their health. Many of these commenters further recommended that the AQI value of 100 should be lowered to 25 μg/m³ even if the standard is retained. Commenters expressed the view that this would more adequately allow the public to take health-protective actions.

The EPA disagrees with these commenters and notes that many State, Tribal and local air agencies have expressed strong support for aligning the 100 breakpoint of the AQI with the short-term 24-hour primary $PM_{2.5}$ standards as discussed in the proposal (88 FR 5558, January 27, 2023). The EPA agrees with the view, expressed by State, local and Tribal entities, that aligning the lower breakpoints with the standards enables clear communication of the standards. This alignment approach is also utilized in the other AQI sub-indices lower breakpoints and taking a different approach with the $PM_{2.5}$ AQI could cause confusion. Additionally, the Administrator has judged that it is appropriate to retain the 24-hour standard at a level of 35 μg/m³ (in conjunction with the other primary standards) to protect public health with an adequate margin of safety, based on the health evidence discussed in section II.A.2. Thus, EPA disagrees that it is necessary or appropriate to set the 100 breakpoint at a lower concentration to provide further information to the public. The 50 breakpoint, which is set at a level below 25 μg/m³, will continue to provide information to members of the public particularly concerned about exposures to $PM_{2.5}$. As with the 50 breakpoint, aligning the breakpoint with the standard both reflects the Administrator's judgment about the health risks and eliminates the potential to cause confusion in the public about those risks.

b. Air Quality Index Values of 200 and Above

Some commenters supported the proposed revisions to the 200, 300 and 500 breakpoints that recognize the expanded body of scientific evidence, particularly several new epidemiologic studies conducted during high pollution events such as wildfires and multiple controlled human exposure studies. A few commenters agreed with incorporating the expanded body of scientific evidence into the 200, 300 and 500 breakpoints, but suggested a modified linear approach between 200 (115 μg/m³) and 500 (312 μg/m³, setting the 300 breakpoint to 187 μg/m³) based on recent epidemiologic wildfire smoke studies.

Other commenters disagreed with the proposed revisions and suggested the EPA should continue using the previous breakpoints that follow the 1999 linear approach (64 FR 42530, August 4, 1999), because not changing the breakpoints would simplify communications. A few commenters stated the proposed revisions to the AQI upper breakpoints are not justified because the scientific evidence supporting the revisions is inadequate. To support this view, the commenters suggest that only three epidemiologic studies were used in determining the upper breakpoints and none of them were representative of potential effects in the general public; of the 13 studies cited only three were near the proposed revised breakpoints; four of the studies involved exposure to PM from diesel and traffic pollution, which is different than PM from wildfire smoke; and the data supporting the revisions only indicated ''mild'' health effects that were mostly in sensitive populations.

The EPA agrees with the majority of commenters that supported utilizing the expanded body of scientific evidence to revise the 200, 300 and 500 breakpoints of the AQI. The EPA appreciates the suggestion of using a revised linear approach from 200 to 500. But rather than using the available evidence to only set the breakpoint of 500, the EPA finds it appropriate to set the breakpoints for 200, 300 and 500 using an evidence-based approach, by relying on information presented in both controlled human exposure studies and epidemiologic studies that examine relationships between high $PM_{2.5}$ exposure episodes (*i.e.,* periods of wildfire smoke) and various health outcomes. Setting these breakpoints based directly on health effects evidence, which can be communicated, is more useful and appropriate than using a linear approach, because it can better describe the potential health effects and symptoms which also helps the public better understand why more health protective actions are needed. By its nature, a linear approach does not evaluate and identify associated health effects and risk factors.

The EPA disagrees with the commenters that expressed the view that these upper breakpoints should not be revised based largely on the numerous peer-reviewed studies published since the 200, 300 and 500 breakpoints were originally established in 1999 (64 FR 42530, August 4, 1999). As discussed in the proposal (88 FR 5641, January 27, 2023), the rationale behind the proposed revisions is rooted in the fact the upper AQI breakpoints are based on outdated scientific evidence. Specifically, the traditional linear approach was predicated on the 500 value of the AQI, which was estimated using health studies that used the British Smoke Method. The British Smoke Method is based on a particle size fraction (4.5 microns) that is larger

than $PM_{2.5}$. Given that the British Smoke method has a larger particle size cutpoint than the current $PM_{2.5}$ monitoring method, which has a cutpoint of 2.5 microns, a concentration of 500 μg/m^3 based on the British Smoke method would be equivalent to a lower $PM_{2.5}$ concentration (88 FR 5641, January 27, 2023). The combination of a larger particle size fraction informing previous decisions around upper AQI breakpoints and more recent scientific evidence than the London Fog Episode, on the potential health consequences of what we currently consider to be high $PM_{2.5}$ exposures, provides the underlying basis for revising the upper breakpoints to better inform the public about air quality to allow the public to take health protective actions as appropriate. Moreover, as discussed above, until recently there was limited information upon which to base the breakpoints between 150 and 500, so the linear approach was a reasonable substitute. While not changing the breakpoints may be easier because there is no change to communicate, using a health-based approach is more appropriate, because it helps the public better understand that more health protective actions are needed.

The Agency disagrees that the scientific evidence discussed in the proposal is inadequate to revise the 200, 300 and 500 breakpoints of the AQI (88 FR 5640, January 27, 2023). The EPA disagrees that these studies should not be considered because they ''indicated mild health effects in sensitive populations.'' The EPA notes that many of the subclinical effects discussed in the proposal (88 FR 5640, January 27, 2023) that informed the breakpoints are on the biologically plausible pathway (see 2019 ISA, section 6.1.1 and Figure 6–1) to more severe cardiovascular outcomes, such as ED visits, hospital admissions, and death as depicted in the large number of epidemiologic studies evaluated in the 2019 ISA and ISA Supplement. From a public health perspective, the purpose of the AQI is to inform the public when air quality could adversely affect their health. The scientific evidence informed revisions to the breakpoints at the upper end of the AQI allow it to better reflect the risk of experiencing health effects at higher $PM_{2.5}$ concentrations. In addition, the EPA disagrees with the commenter that the effects reported at these higher concentrations were observed only in sensitive populations as these effects were also reported in healthy populations (Ghio et al., 2000; Ghio et al., 2003; Urch et al., 2010; Ramanathan et al., 2016; Sivagangabalan et al., 2011; Brook et al., 2009; Bellavia et al. (2013); Tong et al. (2015); Behbod et al. (2013); Vieira et al. (2016a) Vieira et al. (2016b); and Lucking et al. (2011)).

c. Other Comments

The EPA received a few additional comments on elements of the $PM_{2.5}$ AQI, including the averaging time. Some commenters expressed the view that the 24-hour averaging time was not useful when informing the public how to protect their health, particularly during rapidly changing conditions such as wildfire smoke events. Instead, they suggested a subdaily averaging time of 1–3 hours would be more effective because it more closely aligns with how people breathe.

A few of these commenters suggested that instead of changing the AQI averaging time, which aligns with the short-term standard, the EPA could create a public health warning system for unhealthy $PM_{2.5}$ levels. The commenters noted that aligning the AQI averaging time with the short-term standard could be useful for consistent communication with the standards and attainment but suggested that a subdaily warning system could better allow the public to take health protective actions.

The EPA disagrees that a shorter averaging period for the $PM_{2.5}$ AQI sub-index would be better. The health effects evidence supporting a subdaily metric is limited and inconsistent. As part of its review of the health effects evidence, the 2019 ISA evaluated whether a subdaily metric would be more closely related to health effects. Most epidemiologic studies that examined the relationship between short-term $PM_{2.5}$ exposures and health effects evaluated an exposure metric averaged over 24-hours. Some recent studies, focusing on respiratory and cardiovascular effects and mortality, have examined whether there is evidence that subdaily exposure metrics are more closely related to health effects than a traditional 24-hour average metric. After evaluating this limited newer evidence, the 2019 ISA concluded that ''collectively, the available evidence does not indicate that subdaily averaging periods for $PM_{2.5}$ are more closely associated with health effects than the 24-hour avg exposure metric,'' (2019 ISA, chapter 1, section 1.5.2.1, pp. 146–147; U.S. EPA, 2022a).

In addition, there are communication benefits to aligning the averaging time of the AQI with the daily standard, as some of these commenters note, such as providing consistent messages about when it may be beneficial for people to take actions to reduce $PM_{2.5}$ exposures. Furthermore, with regard to an additional warning system, the EPA is concerned that having two air quality communication systems operating at the same time would likely be confusing to the public and reduce the effectiveness of the systems.

At the same time, the EPA recognizes that when air quality is rapidly changing, such as during wildfire smoke events, reporting information based on a 24-hour metric may not be as useful for the public as reporting more frequently would be. The EPA has balanced concerns about being able to provide timely communication of air quality hazards when conditions are changing quickly with the goal of limiting the number of air quality communications systems and its judgment that the evidence supports a 24-hour-based metric linked to the daily standard by establishing the NowCast, which takes into consideration subdaily $PM_{2.5}$ concentrations and provides a near real-time AQI value based on the AQI colors and scale. Specifically, the NowCast shows air quality conditions for the most current hour of $PM_{2.5}$ data available by using a calculation that involves multiple hours of past data. As noted in the AQI Technical Assistance Document, the NowCast currently uses longer averages during periods of stable air quality and shorter averages (down to a 3-hour average) when air quality is changing rapidly, such as during a wildfire (U.S. EPA, 2018a). As discussed further in section IV.D.2 of this notice, the EPA uses the NowCast to approximate the complete daily AQI (24-hour average) during any given hour. This means the subdaily NowCast is approximating a 24-hour average exposure, which aligns with the health evidence and the existing AQI communications network, while also being capable of communicating rapidly changing conditions to the public.

3. Summary of Final Revisions

Upon reviewing and considering the comments on the proposed revisions (summarized above in Section IV.C) along with the scientific evidence outlined in the proposal (88 FR 5639, January 27, 2023) and summarized above in section IV.A, the EPA is finalizing the proposed changes to the AQI.

Thus, as discussed in section IV of the preamble (88 FR 5639, January 27, 2023) to the proposed rule, the EPA is taking final action to revise the AQI value of 50 to 9.0 μg/m^3, 24-hour average, consistent with the final decision on the primary annual $PM_{2.5}$ standard level as summarized in section II.C of the

preamble to the final rule; retain the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with the final decision on the primary 24-hour $PM_{2.5}$ standard level as summarized in section II.C of the preamble to the final rule; and retain the AQI value of 150 at 55 μg/m^3, 24-hour average. The EPA is also taking action to revise the AQI value of 200 to 125 μg/m^3, 24-hour average; 300 to 225 μg/m^3, 24-hour average; and 500 to 325 μg/m^3, 24-hour average, consistent with the rationale discussed above and the health evidence discussed in section IV of the preamble (88 FR 5639, January 27, 2023) to the proposed rule. The EPA has prepared communications materials to assist States with adjusting to the revised AQI and looks forward to working with, and learning from the experiences of, State, local, and Tribal governments in implementing these changes.

C. Air Quality Index Category Breakpoints for PM_{10}

The EPA proposed to retain the PM_{10} sub-index of the AQI consistent with the proposed decision to retain the primary PM_{10} standard, and consistent with the health effects information that supports this proposed decision, as discussed in section III.D of the proposal (88 FR 5632, January 27, 2023). EPA did not receive comments on this and is taking final action to retain the PM_{10} sub-index of the AQI for the reasons stated in the preamble to the proposed rule (88 FR 5642, January 27, 2023).

D. Air Quality Index Reporting

With respect to the reporting requirements for the AQI and as noted in the proposal (88 FR 5642, January 27, 2023) there have been many technological advances in air quality monitoring and data reporting since the appendix G to 40 CFR part 58 was last revised in 1999. Federal, State, local, and Tribal agencies have used these changes to make health information and air quality data more readily available and easier to access. Given this, it is useful to update the reporting requirements and recommendations to match current practices and ensure the public has the most useful and timely information to take health-protective behaviors.

1. Summary of Proposed Revisions

Currently, appendix G defines daily reporting as five days per week. When this reporting requirement was originated in 1999 the technology available at that time was not sufficient to calculate and report the AQI more than five days per week without requiring additional staffing on the weekends. Since that time, advances in technology have allowed for reporting seven days per week automatically without expending additional resources on weekends. As a result, most State, local, and Tribal air agencies now report the AQI seven days per a week. Given these technological advances and noting that reporting agencies currently report the AQI seven days per week, the EPA proposed that State, local, and Tribal agencies that report the AQI be required to report it seven days a week, ensuring that the members of the public continue to have access to daily air quality and health information that they can use to take steps to protect their health.

Improvements in monitoring networks and modeling capabilities have also enabled the ability to report the AQI in near real-time. This allows State, local, and Tribal air agencies to provide timely air quality information to the public for making health-protective decisions and to help satisfy AQI reporting requirements. The availability of near real-time AQI data also allows for more timely responses by the public when air quality conditions are changing rapidly, such as during wildfire smoke events. Subdaily reporting of the AQI can be critical when there are rapidly change conditions and/or high pollution events so that the public is able to make informed decisions to protect their health. Many State, local, and Tribal air agencies currently report the AQI hourly to ensure that the public has access to accurate and timely information. In recognition of these advances, and to continue to provide for near-real time AQI reporting that the public has come to rely on, the EPA proposed to recommend that State, local, and Tribal agencies report the AQI in near-real time.

In lieu of or along with reporting the near-real-time AQI directly to the public, most State/local and Tribal agencies submit hourly air quality data to the EPA. The EPA and some State, local and Tribal air quality agencies use this near-real-time data to create products for use by the public, weather service providers and the media as discussed in the proposal (88 FR 5643, January 27, 2023). To continue to ensure the availability of the products that the public and many stakeholders rely upon, the EPA proposed to recommend that State, local, and Tribal air quality agencies submit hourly data to the EPA's air quality database. Submitting hourly data to the EPA for use on the AirNow website and in other products also enables State, local, and Tribal air quality agencies to meet the recommendation to report the AQI in near-real-time.

In addition to the proposed updates to the reporting requirements and recommendations for near-real-time reporting and data submission recommendations, the Agency also proposed reformatting the question-and-answer format used in appendix G to align with the current standard formatting used in the Code of Federal Regulations. In proposing to update the format, the EPA did not reopen the language that has merely been moved or rearranged as there are no substantive changes.

Another change the EPA proposed to make to appendix G is with regard to Table 2—Breakpoints for the AQI for purposes of clarity. As discussed in the proposal (88 FR 5642, January 27, 2023) and summarized here, the EPA proposed to collapse the two rows presented for the Hazardous Category into one. The two rows in the current table specify pollutant concentrations for two AQI ranges within the Hazardous category (301–400 and 401–500), with an intermediate break at 400. The 400 breakpoint for all criteria pollutants in the current Table 2 is set at the proportional pollutant concentration approximately halfway between the Index values of 300 and 500. In proposing updated AQI breakpoints for $PM_{2.5}$, the EPA considered adjusting the 400 breakpoint similarly. However, the EPA concluded that collapsing the two rows into a single range (301–500) would provide a more transparent and easy-to-follow presentation of the pollutant concentrations corresponding to the AQI range for the Hazardous category. Moreover, collapsing the Hazardous category into a single row in Table 2 has no substantive effect on the Emergency Episode program in 40 CFR part 51, appendix L. Thus, the EPA proposed to remove the breakpoint of 400 from the table in appendix G but this change would not substantively affect the derivation of the AQI for any pollutant.

In addition, the EPA proposed to move some information currently in appendix G into the Technical Assistance Document for the Reporting of Daily Air Quality, or TAD (U.S. EPA, 2018a), so that it can be updated in a more timely manner to reflect current scientific and health effects evidence and current communication methods, thereby assisting State, local, and Tribal agencies in providing accurate and timely information to the public. Information that was proposed to be moved from appendix G to the TAD included the definitions of the sensitive (at-risk) populations for each pollutant.

This definition is typically evaluated and updated, as warranted, in most NAAQS reviews, even if the standard is not revised. Generally, if the standard is not revised in a review of the NAAQS, then appendix G is also not revised. Moving the definitions of sensitive groups to the TAD allows them to be updated even when a NAAQS is not revised to be consistent with the definitions of the sensitive (at-risk) populations identified in the ISA for that NAAQS review. Also, the proposal (88 FR 5642, January 27, 2023) recognized that the ways that air quality and health information is supplied to the news media and public changes regularly and thus proposed that information about suggested approaches for public communication be taken out of appendix G and discussed in the TAD.

2. Summary of Significant Comments on the Proposed Revisions

The EPA received many comments on the proposed changes to AQI reporting, many of which supported the proposed revisions. EPA discusses several of the topics that received the most attention from commenters below. Discussion of other comments received on the proposed changes to the AQI can be found in section IV of the Responses to Significant Comments on the 2023 Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter.

Most commenters expressed support for revising the definition of ''daily reporting'' from five days a week to seven days a week. A commenter did not support this change and recommended the EPA maintain the definition of daily as five days per week, noting that State and local air agencies do not routinely work seven days per week and would not be available to perform quality control of this data and report it reliably on weekends.

The EPA appreciates the support for this proposed revision and disagrees that the proposed change would require personnel to perform quality control of AQI data on weekends. 40 CFR part 58 Appendix D defines continuous monitoring requirements for agencies participating in the State/Local Air Monitoring Stations (SLAMS) network, and Appendix G states that agencies '' . . . must use concentration data from State/Local Air Monitoring Stations (SLAMS) required by 40 CFR 58.10'' when reporting the AQI. Therefore, as noted in Appendix D and G, Agencies are required to report the AQI using monitors within SLAMS, which are not subject to daily quality control/validation.

A few commenters noted that the proposal preamble language mentioned AQI is reported three ways (88 FR 5637, 5638, January 27, 2023): ''The AQI is reported three ways all of which are useful and complementary. The daily AQI is reported for the previous day and used to observe trends in community air quality, the AQI forecast helps people plan their outdoor activities for the next day, and the near-real-time AQI, or NowCast AQI, tells people whether it is a good time for outdoor activity.'' These commenters suggested that the NowCast is being codified in 40 CFR part 58 Appendix G as a method of calculating the AQI, which they oppose, saying that codifying its use is inappropriate given the shortest averaging period of the $PM_{2.5}$ NAAQS remains at 24-hours. Some stated that NowCast values have no direct correlation to the AQI calculation methodology codified in 40 CFR part 58 Appendix G. These commenters say that codifying the NowCast would impose a significant burden on States' forecasting staff.

However, some other commenters noted they appreciate the public-friendly format and near real-time data the NowCast provides and use it in their clinical encounters with patients. One air agency recognized the importance of the NowCast near real-time AQI during high pollution events and suggested the EPA should provide more ''concrete'' health messaging for these short-term spikes.

The EPA disagrees that the preamble language proposed to codify the NowCast or to impose a burden on reporting agencies. The preamble to the proposed rule references the AQI being reported in three ways and it does so because the EPA and many State, local and Tribal air quality agencies already report it these three ways. However, text included in the preamble is generally explanatory and does not alter regulatory provisions. Comments that State that EPA is codifying the NowCast into Appendix G are incorrect. Further, in proposed revisions to 40 CFR part 58 Appendix G, the EPA recommended, but did not propose to require, the use of air quality forecasts and a subdaily AQI. Consistent with the proposal, the EPA is therefore not finalizing any additional requirement or burden on States' forecasting staff relative to forecasts or a subdaily AQI.

The EPA disagrees with the comment that the NowCast values have no direct correlation to the AQI calculation methodology codified in 40 CFR part 58 Appendix G. As noted in the AQI Technical Assistance Document (Technical Assistance Document for the Reporting of Daily Air Quality—the Air Quality Index (AQI)), the NowCast algorithm is based on the AQI methodology but provides more real-time information to the public (U.S. EPA, 2018a). While the NowCast algorithm is approximating a 24-hour average exposure, it can reflect concentrations observed over shorter averaging times when air quality is changing rapidly (U.S. EPA, 2018a). The EPA reflects the nature of the NowCast in the health messaging provided there.

As noted in the above discussion of the AQI, air quality can change quickly during the day. A central purpose of the AQI is to help the public know when it is prudent to take action to reduce their exposure to pollution. Accordingly, the EPA developed the NowCast to estimate the 24-hour AQI for the current hour to give people information and tools to reduce their exposures to protect their health, particularly when air quality may be changing. The NowCast gives people the knowledge and ability to take timely action. They can use this information to reduce their exposure—reducing exposures if $PM_{2.5}$ is high only during a few hours a day will help reduce a person's 24-hour exposure—or be active when air quality is better.

The first NowCast method was developed in 2003 and was designed so ''current conditions'' represent the 24-hour $PM_{2.5}$ standard as closely as possible. This method proved to be slow to respond during rapid air quality changes. In 2013, the EPA developed an updated NowCast method for $PM_{2.5}$ [141] that responds more quickly to rapidly changing air quality conditions, such as those we see during wildfires, to make air quality alerts more timely. We analyzed millions of data points in developing this NowCast method and presented this information to State, local and Tribal air agencies. The updated NowCast, which is still in use, was launched August 1, 2013, on AirNow.gov. It was designed to represent a shorter average (target 3-hour) when air quality is changing rapidly, in part because 3-hour averages from some continuous monitors are more stable than 1-hour averages. The NowCast reflects a longer-term (12-hour) average when air quality is stable.

After evaluating the 2013 NowCast method, the EPA concluded that it matched the desired characteristics. The NowCast method responds to rapid changes in air quality yet still reflects a

[141] U.S. EPA. (2013). Transitioning to a New NowCast Method. Presentation available in the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072), at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

longer-term average when air quality is stable; will work in any location with adequate air quality data and for any air quality situation; gives people the best possible estimate of a 24-hour exposure; allows the EPA to caution people in time for them to take protective action and reduce their 24-hour exposure; and ensures that AQI maps on AirNow more closely match what people see.

The AQI is designed to allow people to reduce their exposure when pollution levels are higher and be active outdoors when pollution levels are lower. Since air quality almost always changes during the day, that level of granularity is not possible with a 24-hour forecast. If the public has only the 24-hour forecast, they may miss the times to be active outdoors when air quality is better and may be active outdoors when air quality is worse.

Also as noted above, many entities appreciate the near real-time reporting of the AQI that the NowCast provides and suggested more specific messaging is needed. The EPA appreciates this insight and will continue to consider ways to communicate air quality information most effectively to the public. For example, in light of recent wildfire events, the EPA worked with the USFS to pilot the AirNow Fire and Smoke Map.

3. Summary of Final Revisions

Upon reviewing and considering the comments on the proposed revisions (summarized above in Section IV.C) along with the rationale outlined in the proposal (88 FR 5638, January 27, 2023) and summarized above in section IV.C, the EPA is finalizing the proposed changes to the AQI reporting requirements. Thus, as discussed in section IV of the preamble to the proposed rule, the EPA is taking final action to require the AQI be reported seven days a week; recommend that State, local, and Tribal agencies report the AQI in near-real time; recommend that State, local, and Tribal air quality agencies submit hourly data to the EPA's air quality database; reformat appendix G to align with the current standard formatting used in the Code of Federal Regulations; collapse the two rows in Table 2 presented for the Hazardous Category into one by removing the 400 breakpoint; and move some information currently in appendix G into the Technical Assistance Document for the Reporting of Daily Air Quality, or TAD (U.S. EPA, 2018a) such as including the definitions of the sensitive (at-risk) populations for each pollutant and suggested approaches for public communication as stated in the revised Appendix G.

Table 2 below summarizes the breakpoints for the $PM_{2.5}$ sub-index.

TABLE 2—BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX

AQI category	Index values	Breakpoints (μg/m³, 24-hour average)
Good	0–50	0.0–9.0
Moderate	51–100	9.1–35.4
Unhealthy for Sensitive Groups	101–150	35.5–55.4
Unhealthy	151–200	55.5–125.4
Very Unhealthy	201–300	125.5–225.4
Hazardous [1]	301+	225.5

[1] AQI values between breakpoints are calculated using equation 1 in appendix G. For AQI values in the hazardous category, AQI values greater than 500 should be calculated using equation 1 and the $PM_{2.5}$ concentration specified for the AQI value of 500.

V. Rationale for Decisions on the Secondary PM Standards

This section presents the rationale for the Administrator's decision that no change to the current secondary PM standards is required at this time to provide requisite protection against the public welfare effects of PM within the scope of this reconsideration (*i.e.,* visibility, climate, and materials effects).[142] This decision is based on a thorough review of the scientific evidence generally published through December 2017,[143] as presented in the 2019 ISA (U.S. EPA, 2019a), on the non-ecological public welfare effects of PM pertaining to the presence of PM in ambient air, specifically visibility, climate, and materials effects. Additionally, this decision is based on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA, generally through March 2021, as presented in the ISA Supplement [144] (U.S. EPA, 2022a). The selection of welfare effects evaluated within the ISA Supplement was based on the causality determinations reported in the 2019 ISA and the subsequent use of scientific evidence in the 2020 PA.[145]

[142] Consistent with the 2016 Integrated Review Plan (U.S. EPA, 2016), other welfare effects of PM, including ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. Accordingly, the public welfare protection provided by the secondary PM standards against ecological effects such as those related to deposition of nitrogen- and sulfur-containing compounds in vulnerable ecosystems is being considered in that separate review. Thus, the Administrator's decision in this reconsideration will be focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials and hereafter ''welfare effects'' refers to non-ecological welfare effects (*i.e.,* visibility, climate, and materials effects).

[143] In addition to the 2020 review's opening ''call for information'' (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 through approximately January 2018 (U.S. EPA, 2019a, p. ES–2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter.*

[144] As described in more detail in the ISA Supplement, ''the scope of this Supplement provides specific criteria for the types of studies considered for inclusion within the Supplement. Specifically, studies must be peer reviewed and published between approximately January 2018 and March 2021'' (U.S. EPA, 2022a, section 1.2.2).

[145] As described in section 1.2.1 of the ISA Supplement, ''the selection of welfare effects to evaluate within this Supplement is based on the causality determinations reported in the 2019 PM ISA and the subsequent use of scientific evidence in the 2020 PM PA. The 2019 PM ISA concluded a *causal relationship* for each of the welfare effects categories evaluated (*i.e.,* visibility, climate effects, and materials effects). While the 2020 PM PA considered the broader set of evidence for these effects, for climate effects and material effects, it concluded that there remained 'substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects (U.S. EPA, 2020b). Given these uncertainties and limitations, the basis of the discussion on conclusions regarding the secondary standards in the 2020 PM PA primarily focused on visibility effects. Therefore, this Supplement focuses only on visibility effects in evaluating newly available scientific information and is limited to studies

Continued

Specifically, for welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement does not include an evaluation of studies on climate or materials effects. The Administrator's decision also takes into account the 2022 PA evaluation of the policy-relevant information in the 2019 ISA and ISA Supplement and presentation of quantitative analysis of air quality related to visibility impairment; CASAC advice and recommendations, as reflected in discussions of the drafts of the ISA Supplement and 2022 PA at public meetings and in the CASAC's letters to the Administrator; and public comments received on the proposal.

In presenting the rationale for the Administrator's final decision and its foundations, section V.A provides background on the 2020 final decision to retain the secondary PM standards (section V.A.1), and also provides brief summaries of key aspects of the currently available welfare effects evidence (section V.A.2) and quantitative information (section V.A.3). Section V.B summarizes the CASAC's advice (section V.B.1) and the proposed conclusions (section V.B.2), addresses public comments received on the proposal (section V.B.3), and presents the Administrator's conclusions on the adequacy of the current standards (section V.B.4), drawing on consideration of the available scientific and quantitative information, advice from the CASAC, and comments from the public. Section V.C summarizes the Administrator's decision on the secondary PM standards.

A. Introduction

The general approach for this reconsideration of the 2020 final decision on the secondary PM standards relies on the EPA's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgments regarding secondary standards that are requisite to protect the public welfare from known or anticipated adverse effects associated with the pollutant's presence in the ambient air. The EPA's assessments are primarily documented in the 2019 ISA, ISA Supplement, and 2022 PA, which builds on the 2020 PA, all of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 85 FR 4655, January 27, 2020; 86 FR 52673, September 22, 2021; 86 FR 54186, September 30, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022; 87 FR 22207, April 14, 2022; 87 FR 31965, May 26, 2022). In bridging the gap between the scientific assessments of the 2019 ISA and ISA Supplement and the judgments required of the Administrator in determining whether the current standards provide the requisite public welfare protection, the 2022 PA evaluates policy implications of the evaluation of the current evidence in the 2019 ISA and ISA Supplement, and the quantitative information documented in the 2022 PA. In evaluating the public welfare protection afforded by the current standards against PM-related effects within the scope of this reconsideration, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. In reaching conclusions with regard to the standard, the decision draws on the scientific information and analyses about welfare effects, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which scientists agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

1. Background on the Current Standards

The current secondary PM standards were retained in 2020 based on the scientific and technical information available at that time, as well as the then-Administrator's judgments regarding the available welfare effects evidence, the appropriate degree of public welfare protection for the existing standards, and available air quality information on visibility impairment that may be allowed by such a standard (85 FR 82684, December 18, 2020). With the 2020 decision, the then-Administrator retained the secondary 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, the annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$, and the 24-hour PM_{10} standard, with its level of 150 $\mu g/m^3$. The subsections below focus on the key considerations and the then-Administrator's conclusions in the 2020 final decision for climate and materials effects (section V.A.1.a) and visibility effects (section V.A.2.b).

a. Non-Visibility Effects

In light of the robust evidence base, the 2019 ISA concluded there to be causal relationships between PM and climate effects and materials effects (U.S. EPA, 2019a, sections 13.3.9 and 13.4.2). The 2020 final decision was based on a thorough review in the 2019 ISA of the scientific information on PM-induced climate and materials effects. The decision also took into account: (1) Assessments in the 2020 PA of the most policy-relevant information in the 2019 ISA regarding evidence of adverse effects of PM to climate and materials, (2) uncertainties in the available evidence to inform a quantitative assessment of PM-related climate and materials effects, (3) CASAC advice and recommendations, and (4) public comments received during the development of these documents and on the proposal document.

In considering non-visibility welfare effects in the 2020 decision, the then-Administrator concluded that, while it is important to maintain an appropriate degree of control of fine and coarse particles to address non-visibility welfare effects, ''it is generally appropriate to retain the existing standards and that there is insufficient information to establish any distinct secondary PM standards to address climate and materials effects of PM'' (85 FR 82744, December 18, 2020).

With regard to climate, the then-Administrator recognized that there were a number of improvements and refinements to climate models since the 2012 review. However, while the evidence continued to support a causal relationship between PM and climate effects, the then-Administrator noted that significant limitations continued to exist related to quantifying the contributions of direct and indirect

conducted in the U.S. and Canada'' (U.S. EPA, 2022a, section 1.2.1).

effects of PM and PM components on climate forcing (U.S. EPA, 2020b, sections 5.2.2.1.1 and 5.4). He also recognized that the models continued to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km) as compared to simulations at global scales. Therefore, the resulting uncertainty led the then-Administrator to conclude in the 2020 decision that the available scientific information remained insufficient to quantify climate impacts associated with particular concentrations of PM in ambient air (U.S. EPA, 2020b, section 5.2.2.2.1) or to evaluate or consider a level of PM air quality in the U.S. to protect against climate effects and that there was insufficient information available to base a national ambient standard on climate impacts (85 FR 82744, December 18, 2020).

With regard to materials effects, the then-Administrator noted that the evidence available in the 2019 ISA continued to support a causal relationship between materials effects and PM deposition (U.S. EPA, 2019a, section 13.4). He recognized that the deposition of fine and coarse particles to materials can lead to physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the natural weathering processes and by promoting the corrosion of metals, the degradation of building materials, and the weakening of material components. While some new information was available in the 2019 ISA, the information was from studies primarily conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2020b, section 13.4). Additionally, the information assessed in the 2019 ISA did not support quantitative analyses of PM-related materials effects in the 2020 PA (U.S. EPA, 2020b, section 5.2.2.2.2). Given the limited amount of information available and its inherent uncertainties and limitations, the Administrator concluded that he was unable to relate soiling or damage to specific levels of PM in ambient air or to evaluate or consider a level of air quality to protect against such materials effects, and that there was insufficient information available to support a distinct national ambient standard based on materials effects (85 FR 82744, December 18, 2020).

In reviewing the 2019 draft PA, the CASAC agreed with staff conclusions that, while these effects are important, ''the available evidence does not call into question the protection afforded by the current secondary PM standards'' and recommended that the secondary standards ''should be retained'' (Cox, 2019b, p. 3 of letter). In reaching a final decision in 2020, for all of the reasons discussed above and recognizing the CASAC conclusion that the evidence provided support for retaining the current secondary PM standards, the then-Administrator concluded that it was appropriate to retain the existing secondary PM standards, without revision. For climate and materials effects, this conclusion reflected his judgment that, although it remains important to maintain secondary $PM_{2.5}$ and PM_{10} standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, there was insufficient information to establish distinct secondary PM standards to address non-visibility PM-related welfare effects (85 FR 82744, December 18, 2020).

b. Visibility Effects

The 2019 ISA concluded that, ''the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2019a, section 13.2.6). The 2020 decision on the adequacy of the secondary standards with regard to visibility effects was a public welfare policy judgment made by the then-Administrator, which drew upon the available scientific evidence for PM-related visibility effects and on analyses of visibility impairment, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. The 2020 final decision was based on a thorough review in the 2019 ISA of the scientific information on PM-related visibility effects. The decision also took into account: (1) Assessments in the 2020 PA of the most policy-relevant information in the 2019 ISA regarding evidence of adverse effects of PM on visibility; (2) air quality analyses of the $PM_{2.5}$ visibility index and design values based on the form and averaging time of the existing secondary 24-hour $PM_{2.5}$ standard; (3) CASAC advice and recommendations; and (4) public comments received during the development of these documents and on the 2020 proposal document.

In considering the visibility effects in the 2020 review, the then-Administrator noted the long-standing body of evidence for PM-related visibility impairment. This evidence, which is based on the fundamental relationship between light extinction and PM mass, demonstrated that ambient PM can impair visibility in both urban and remote areas, and had changed very little since the 2012 review (U.S. EPA, 2019a, section 13.1; U.S. EPA, 2009a, section 9.2.5). The evidence related to public perception of visibility impairment was from studies from four areas in North America.[146] These studies provided information to inform our understanding of levels of visibility impairment that the public judged to be ''acceptable'' (U.S. EPA, 2010b; 85 FR 24131, April 30, 2020). In considering these public preference studies, the then-Administrator noted that no new visibility studies conducted in the U.S. were discussed in the 2019 ISA, and there was little newly available information with regard to acceptable levels of visibility impairment in the U.S. The Administrator recognized that visibility impairment can have implications for people's enjoyment of daily activities and their overall well-being, and therefore, considered the degree to which the current secondary standards protect against PM-related visibility impairment.

Consistent with the 2012 review, in the 2020 review, the then-Administrator first concluded that a target level of protection for a secondary PM standard is most appropriately defined in terms of a visibility index that directly takes into account the factors (*i.e.,* species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. In defining a target level of protection, the then-Administrator considered the specific aspects of such an index, including the appropriate indicator, averaging time, form and level (78 FR 82742–82744, December 18, 2020).

First, with regard to indicator, the then-Administrator noted that in the 2012 review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using an adjusted version of the IMPROVE algorithm, which allows the estimation of the light extinction using routinely monitored components of $PM_{2.5}$, $PM_{10-2.5}$ mass, and estimates of relative humidity. The then-Administrator recognized that, while there have been some revisions to the IMPROVE algorithm since the time of the 2012

[146] Preference studies were available in four urban areas. Three western preference studies were available, including one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates, 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009). More details about these studies are available in Appendix D of the 2022 PA (U.S. EPA, 2022b).

review, our fundamental understanding of the relationship between PM in ambient air and light extinction had changed little and the various IMPROVE algorithms appropriately reflected this relationship across the U.S. In the absence of a monitoring network for direct measurement of light extinction, he concluded that a calculated light extinction indicator that utilizes the IMPROVE algorithms continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment (78 FR 82742–82744, December 18, 2020).

In further defining the characteristics of a visibility index, the then-Administrator next considered the appropriate averaging time, form, and level of the index. Given the available scientific information the review, and in considering the CASAC's advice and public comments, the then-Administrator concluded that, consistent with the decision in the 2012 review, a visibility index with a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values remained reasonable. With regard to the averaging time and form of such an index, the Administrator noted analyses conducted in the last review that demonstrated relatively strong correlations between 24-hour and subdaily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction (78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the subdaily time periods of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. This decision in the 2020 review also recognized that a 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). The then-Administrator recognized that there was no new information to support updated analyses of this nature, and therefore, he believed these analyses continued to provide support for consideration of a 24-hour averaging time for a visibility index in this review. With regard to the statistical form of the index, the Administrator noted that, consistent with the 2012 review: (1) A multi-year percentile form offers greater stability from the occasional effect of interannual meteorological variability (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58); (2) a 90th percentile represents the median of the distribution of the 20 percent worst visibility days, which are targeted in Federal Class I areas by the Regional Haze Program; and (3) public preference studies did not provide information to identify a different target than that identified for Federal Class I areas (U.S. EPA, 2011, p. 4–59). Therefore, the then-Administrator judged that a visibility index based on estimates of light extinction, with a 24-hour averaging time and a 90th percentile form, averaged over three years, remained appropriate (78 FR 82742–82744, December 18, 2020).

With regard to the level of a visibility index, consistent with the 2012 review, the then-Administrator judged that it was appropriate to establish a target level of protection of 30 deciviews (dv),[147] [148] reflecting the upper end of the range of visibility impairment judged to be acceptable by at least 50% of study participants in the available public preference studies (78 FR 3226, January 15, 2013). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time (U.S. EPA, 2011, section 4.3.4). At the time of the 2012 review, the then-Administrator noted a number of uncertainties and limitations in public preference studies, including the small number of stated preference studies available, the relatively small number of study participants, the extent to which the study participants may not be representative of the broader study area population in some of the studies, and the variations in the specific materials and methods used in each study. In considering the available preference studies in 2012, with their inherent uncertainties and limitations, the then-Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target level of protection based on the upper end of the range of candidate protection levels (CPLs).

Given that there were no new preference studies in the 2019 ISA, the then-Administrator's judgments in 2020 were based on the same studies, with the same range of levels, available in the 2012 review. The 2020 PA (U.S. EPA, 2020b, section 5.5), discussed a number of limitations and uncertainties associated with these studies. In considering the scientific information, with its uncertainties and limitations, as well as public comments on the level of the target level of protection against visibility impairment, the then-Administrator concluded that it was appropriate to again use a level of 30 dv for the visibility index (78 FR 82742–82744, December 18, 2020).

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, was requisite to protect public welfare with regard to visual air quality, the Administrator next considered the degree of protection from visibility impairment afforded by the existing suite of secondary PM standards.

In this context, the then-Administrator considered the updated analyses of visibility impairment presented in the 2020 PA (U.S. EPA, 2020b, section 5.2.1.2), which reflected a number of improvements since the 2012 review. Specifically, the updated analyses examined multiple versions of the IMPROVE equation, including the version incorporating revisions since the time of the 2012 review. These updated analyses provided a further understanding of how variation in the inputs to the algorithms affect the estimates of light extinction (U.S. EPA, 2020b, Appendix D). Additionally, for a subset of monitoring sites with available $PM_{10-2.5}$ data, the updated analyses better characterized the influence of coarse PM on light extinction than in the 2012 review (U.S. EPA, 2020b, section 5.2.1.2).

The results of the updated analyses in the 2020 PA were consistent with those from the 2012 review. Regardless of which version of the IMPROVE equation was used, the analyses demonstrated that, based on 2015–2017 data, the 3-year visibility metric was at or below about 30 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard, and below 25 dv in most of those areas. In locations with available $PM_{10-2.5}$ monitoring, which met both the current 24-hour secondary $PM_{2.5}$ and PM_{10} standards, 3-year visibility index metrics were at or below 30 dv regardless of whether the coarse fraction was included as an input to the algorithm for estimating light extinction (U.S. EPA, 2020b, section 5.2.1.2). While the inclusion of the coarse fraction had a relatively modest impact on the estimates of light extinction, the then-Administrator recognized the continued importance of the PM_{10} standard given the potential for larger impacts on light extinction in areas with higher coarse particle concentrations, which were not included in the analyses in the 2020 PA due to a lack of available data (U.S. EPA, 2019a, section 13.2.4.1; U.S. EPA, 2020b, section 5.2.1.2). He

[147] Deciview (dv) refers to a scale for characterizing visibility that is defined directly in terms of light extinction. The deciview scale is frequently used in the scientific and regulatory literature on visibility.

[148] For comparison, 20 dv, 25 dv, and 30 dv are equivalent to 64, 112, and 191 megameters (Mm^{-1}), respectively.

noted that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m^3, had visual air quality at least as good as 30 dv, based on the visibility index. Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour $PM_{2.5}$ standard. Thus, the then-Administrator judged that the 24-hour $PM_{2.5}$ standard provided sufficient protection in all areas against the effects of visibility impairment, *i.e.,* that the existing 24-hour $PM_{2.5}$ standard would provide at least the target level of protection for visual air quality of 30 dv which he judged appropriate (78 FR 82742–82744, December 18, 2020).

2. Overview of Welfare Effects Evidence

The information summarized here is based on the scientific assessment of the welfare effects evidence available in this reconsideration; this assessment is documented in the 2019 ISA and ISA Supplement and its policy implications are further discussed in the 2022 PA. While the 2019 ISA provides the broad scientific foundation for this reconsideration, additional literature has become available since the cutoff date of the 2019 ISA that expands the body of evidence related to visibility effects that can inform the Administrator's judgment on the adequacy of the current secondary PM standards. As such, the ISA Supplement builds on the information in the 2019 ISA with a targeted identification and evaluation of new scientific information regarding visibility effects. As described in the ISA Supplement and the 2022 PA, the selection of welfare effects to evaluate within the ISA Supplement were based on the causality determinations reported in the 2019 ISA and the subsequent use of scientific evidence in the 2020 PA (U.S. EPA, 2019a, section 1.2; U.S. EPA, 2022a, section 1.4.2). The ISA Supplement focuses on U.S. and Canadian studies that provide new information on public preferences for visibility impairment and/or developed new methodologies or conducted quantitative analyses of light extinction (U.S. EPA, 2022a, section 1.2). Such studies of visibility effects and quantitative relationships between visibility impairment and PM in ambient air were considered to be of greatest utility in informing the Administrator's conclusions on the adequacy of the current secondary PM standards. The visibility effects evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 final decision on the secondary PM standards for visibility effects. For climate and materials effects, the 2020 PA concluded that there were substantial uncertainties associated with the quantitative relationships with PM concentrations and the concentration patterns that limited the ability to quantitatively assess the public welfare protection provided by the standards from these effects. Therefore, the evaluation of the information related to these effects draws heavily from the 2019 ISA and 2020 PA. The subsections below briefly summarize the nature of PM-related visibility (section V.B.1.a), climate (section V.B.1.b), and materials (section V.B.1.c) effects.

a. Nature of Effects

Visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being (U.S. EPA, 2009a, section 9.2). The strongest evidence for PM-related visibility impairment comes from the fundamental relationship between light extinction and PM mass (U.S. EPA, 2009a), which confirms a well-established ''causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2009a, p. 2–28). Beyond its effects on visibility, the 2009 ISA also identified a causal relationship ''between PM and climate effects, including both direct effects of radiative forcing and indirect effects that involve cloud and feedbacks that influence precipitation formation and cloud lifetimes'' (U.S. EPA, 2009a, p. 2–29). The evidence also supports a causal relationship between PM and effects on materials, including soiling effects and materials damage (U.S. EPA, 2009a, p. 2–31).

The evidence available in this reconsideration is consistent with the evidence available at the time of the 2012 and 2020 reviews and supports the conclusions of causal relationships between PM and visibility, climate, and materials effects (U.S. EPA, 2019a, chapter 13). Evidence newly available in this reconsideration augments the previously available evidence of the relationship between PM and visibility impairment (U.S. EPA, 2019a, section 13.2; U.S. EPA, 2022a, section 4), climate effects (U.S. EPA, 2019a, section 13.3), and materials effects (U.S. EPA, 2019a, section 13.4).

i. Visibility

The fundamental relationship between light extinction and PM mass, and the EPA's understanding of this relationship, has changed little since the 2009 ISA (U.S. EPA, 2009a). The combined effect of light scattering and absorption by particles and gases is characterized as light extinction, *i.e.,* the fraction of light that is scattered or absorbed per unit of distance in the atmosphere.[149] Light extinction is measured in units of 1/distance, which is often expressed in the technical literature as visibility per megameter (abbreviated Mm^{-1}). Higher values of light extinction (usually given in units of Mm^{-1} or dv) correspond to lower visibility. When PM is present in the air, its contribution to light extinction is typically much greater than that of gases (U.S. EPA, 2019a, section 13.2.1). The impact of PM on light scattering depends on particle size and composition, as well as relative humidity. All particles scatter light, as described by the Mie theory, which relates light scattering to particle size, shape, and index of refraction (U.S. EPA, 2019a, section 13.2.3; Mie, 1908, Van de Hulst, 1981). Fine particles scatter more light than coarse particles on a per unit mass basis and include sulfates, nitrates, organics, light-absorbing carbon, and soil (Malm et al., 1994). Hygroscopic particles like ammonium sulfate, ammonium nitrate, and sea salt increase in size as relative humidity increases, leading to increased light scattering (U.S. EPA, 2019a, section 13.2.3).

As at the time of the 2012 and 2020 reviews, direct measurements of PM light extinction, scattering, and absorption continue to be considered more accurate for quantifying visibility than PM mass-based estimates because measurements do not depend on assumptions about particle characteristics (*e.g.,* size, shape, density, component mixture, etc.) (U.S. EPA, 2019a, section 13.2.2.2). Measurements of light extinction can be made with high time resolution, allowing for characterization of subdaily temporal patterns of visibility impairment. A number of measurement methods have been used for visibility impairment (*e.g.,*

[149] All particles scatter light and, although a larger particle scatters more light than a similarly shaped smaller particle of the same composition, the light scattered per unit of mass is greatest for particles with diameters from ~0.3–1.0 μm (U.S. EPA, 2009a, section 2.5.1; U.S. EPA, 2019a, section 13.2.1). Particles with hygroscopic components (*e.g.,* particulate sulfate and nitrate) contribute more to light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to relative humidity.

transmissometers, integrating nephelometers, teleradiometers, telephotometers, and photography and photographic modeling), although each of these methods has its own strengths and limitations (U.S. EPA, 2019a, Table 13–1). While some recent research confirms and adds to the body of knowledge regarding direct measurements as is described in the 2019 ISA and ISA Supplement, no major new developments have been made with these measurement methods since prior reviews (U.S. EPA, 2019a, section 13.2.2.2; U.S. EPA, 2022a, section 4.2).

In the absence of a robust monitoring network for the routine measurement of light extinction across the U.S., estimation of light extinction based on existing PM monitoring can be used. The theoretical relationship between light extinction and PM characteristics, as derived from Mie theory (U.S. EPA, 2019a, Equation 13.5), can be used to estimate light extinction by combining mass scattering efficiencies of particles with particle concentrations (U.S. EPA, 2019a, section 13.2.3; U.S. EPA, 2009a, sections 9.2.2.2 and 9.2.3.1). This estimation of light extinction is consistent with the method used in previous reviews. The algorithm used to estimate light extinction, known as the IMPROVE algorithm,[150] provides for the estimation of light extinction (b_{ext}), in units of Mm^{-1}, using routinely monitored components of fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) PM. Relative humidity data are also needed to estimate the contribution by liquid water that is in solution with the hygroscopic components of PM. To estimate each component's contribution to light extinction, their concentrations are multiplied by extinction coefficients and are additionally multiplied by a water growth factor that accounts for their expansion with moisture. Both the extinction efficiency coefficients and water growth factors of the IMPROVE algorithm have been developed by a combination of empirical assessment and theoretical calculation using particle size distributions associated with each of the major aerosol components (U.S. EPA, 2019a, sections 13.2.3.1 and 13.2.3.3).

At the time of the 2012 review, two versions of the IMPROVE algorithm were available in the literature—the original IMPROVE algorithm (Lowenthal and Kumar, 2004, Malm and Hand, 2007, Ryan et al., 2005) and the revised IMPROVE algorithm (Pitchford et al., 2007). As described in detail in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.1) and the 2019 ISA (U.S. EPA, 2019a, section 13.2.3), the algorithm has been further evaluated and refined since the time of the 2012 review (Lowenthal and Kumar, 2016), particularly for PM characteristics and relative humidity in remote areas. All three versions of the IMPROVE algorithm were considered in evaluating visibility impairment in this reconsideration.

Consistent with the evidence available at the time of the 2012 and 2020 reviews, our understanding of public perception of visibility impairment comes from visibility preference studies conducted in four areas in North America.[151] The detailed methodology for these studies are described in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.1), the 2019 ISA (U.S. EPA, 2019a), and the 2009 ISA (U.S. EPA, 2019a). In summary, the study participants were queried regarding multiple images that were either photographs of the same location and scenery that had been taken on different days on which measured extinction data were available or digitized photographs onto which a uniform ''haze'' had been superimposed. Results of the studies indicated a wide range of judgments on what study participants considered to be acceptable visibility across the different study areas, depending on the setting depicted in each photograph. Based on the results of the four cities, a range encompassing the $PM_{2.5}$ visibility index values from images that were judged to be acceptable by at least 50 percent of study participants across all four of the urban preference studies was identified (U.S. EPA, 2010b, p. 4–24; U.S. EPA, 2020b, Figure 5–2). Much lower visibility (considerably more haze resulting in higher values of light extinction) was considered acceptable in Washington, DC, than was in Denver, and 30 dv reflected the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants (78 FR 3226–3227, January 15, 2013).

Since the completion of the 2009 and 2019 ISAs, there has been only one public preference study that has become available in the U.S. This study uses images of the Grand Canyon, AZ, described in the ISA Supplement (U.S. EPA, 2022a). The Grand Canyon study, conducted by Malm et al. (2019), has a similar study design to that used in the public preference studies discussed above; however, there are several important differences that make it difficult to directly compare the results of the Malm et al. (2019) study with other public preference studies. As an initial matter, the Grand Canyon study was conducted in a Federal Class I area, as opposed to in an urban area, with a scene depicted in the photographs that did not include urban features.[152] We recognize that public preferences with respect to visibility in Federal Class 1 areas may well differ from visibility preferences in urban areas and other contexts, although there is currently a lack of information to on such questions. Further, the Malm et al. (2019) study also used a much lower range of superimposed ''haze'' than the preference studies discussed above.[153] It is unclear whether the participant preferences are a function in part of the range of potential values presented, such that the participant preferences for the Grand Canyon were generally lower[154] than the other preference studies in part because of the lower range of superimposed ''haze'' for the images in that study, or if their preferences would vary if presented with images with a range of superimposed ''haze'' more comparable to the levels used in the other studies (*i.e.,* more ''haze'' superimposed on the images).

The Malm et al. (2019) study also explored alternate methods for evaluating ''acceptable'' levels of visual air quality from the preference studies, including the use of scene-specific visibility indices as potential indicators of visibility levels as perceived by the observer (Malm et al., 2019). In addition to measures of atmospheric haze, such

[150] The algorithm is referred to as the IMPROVE algorithm as it was developed specifically to use monitoring data generated at IMPROVE network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of monitoring sites that make those measurements (Malm et al., 1994).

[151] Preference studies were available in four urban areas in the last review: Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2001; Smith and Howell, 2009).

[152] The Grand Canyon study used a single scene looking west down the canyon with a small landscape feature of a 100-km-distant mountain (Mount Trumbull), along with other closer landscape features. The scenes presented in the previously available visibility preference studies are presented in more detail in Table D–9 in the 2022 PA (U.S. EPA, 2022b, Appendix D).

[153] The Grand Canyon study superimposed light extinction ranging from 3 dv to 20 dv on the image slides shown to participants compared to the previously available preference studies. In those studies, the visibility ranges presented were as low as 9 dv and as high as 45 dv. The visibility ranges presented in the previously available visibility preference studies are described in more detail in Table D–9 in the 2022 PA (U.S. EPA, 2022b, Appendix D).

[154] In the Grand Canyon study, the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants was 7 dv (Malm et al., 2019).

as atmospheric extinction, used in previously available preference studies, other indices for visual air quality include color and achromatic contrast of single landscape figures, average and equivalent contrast of an entire scene, edge detection algorithms such as the Sobel index, and just-noticeable difference or change indexes. The results reported by Malm et al. (2019) suggest that scene-dependent metrics, such as contrast, may be useful alternate predictors of preference levels compared to universal metrics like light extinction (U.S. EPA, 2022a, section 4.2.1). This is because extinction alone is not a measure of ''haze,'' but of light attenuation per unit distance, and visible ''haze'' is dependent on both light extinction and distance to a landscape feature (U.S. EPA, 2022a, section 4.2.1). However, there are very few studies available that use scene-dependent metrics (*i.e.,* contrast) to evaluate public preference information, which makes it difficult to evaluate them as an alternative to the light extinction approach.

ii. Climate

The available evidence continues to support the conclusion of a causal relationship between PM and climate effects (U.S. EPA, 2019a, section 13.3.9). Since the 2012 review, climate impacts have been extensively studied and recent research reinforces and strengthens the evidence evaluated in the 2009 ISA. Recent evidence provides greater specificity about the details of radiative forcing effects [155] and increases the understanding of additional climate impacts driven by PM radiative effects. The Intergovernmental Panel on Climate Change (IPCC) assesses the role of anthropogenic activity in past and future climate change, and since the completion of the 2009 ISA, has issued the Fifth IPCC Assessment Report (AR5; IPCC, 2013), which summarizes any key scientific advances in understanding the climate effects of PM since the previous report. As in the 2009 ISA, the 2019 ISA draws substantially on the IPCC report to summarize climate effects. As discussed in more detail in the 2022 PA (U.S. EPA, 2022b, section 5.3.2.1.1), the general conclusions are similar between the IPCC AR4 and AR5 reports with regard to effects of PM on global climate. Consistent with the evidence available in the 2012 review, the key components, including sulfate, nitrate, organic carbon (OC), black carbon (BC), and dust, that contribute to climate processes vary in their reflectivity, forcing efficiencies, and direction of forcing. Since the completion of the 2009 ISA, the evidence base has expanded with respect to the mechanisms of climate responses and feedbacks to PM radiative forcing; however, the recently published literature assessed in the 2019 ISA does not reduce the considerable uncertainties that continue to exist related these mechanisms.

As described in the proposal (88 FR 5650, January 27, 2023), PM has a very heterogeneous distribution globally and patterns of forcing tend to correlate with PM loading, with the greatest forcings centralized over continental regions. The climate response to this PM forcing, however, is more complicated since the perturbation to one climate variable (*e.g.,* temperature, cloud cover, precipitation) can lead to a cascade of effects on other variables. While the initial PM radiative forcing may be concentrated regionally, the eventual climate response can be much broader spatially or be concentrated in remote regions, and may be quite complex, affecting multiple climate variables with possible differences in the direction of the forcing in different regions or for different variables (U.S. EPA, 2019a, section 13.3.6). The complex climate system interactions lead to variation among climate models, which have suggested a range of factors that can influence large-scale meteorological processes and may affect temperature, including local feedback effects involving soil moisture and cloud cover, changes in the hygroscopicity of the PM, and interactions with clouds (U.S. EPA, 2019a, section 13.3.7). As a result, there remains insufficient evidence to related climate effects to specific PM levels in ambient air or to establish a quantitative relationship between PM and climate effects, particularly at a regional scale. Further research is needed to better characterize the effects of PM on regional climate in the U.S. before PM climate effects can be quantified.

iii. Materials

Consistent with the evidence assessed in the 2009 ISA, the available evidence continues to support the conclusion that there is a causal relationship between PM deposition and materials effects. Effects of deposited PM, particularly sulfates and nitrates, to materials include both physical damage and impaired aesthetic qualities, generally involving soiling and/or corrosion (U.S. EPA, 2019a, section 13.4.2). Because of their electrolytic, hygroscopic, and acidic properties and their ability to sorb corrosive gases, particles contribute to materials damage by adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, degradation of painted surfaces, deterioration of building materials, and weakening of material components.[156] There is a limited amount of recently available data for consideration in this review from studies primarily conducted outside of the U.S. on buildings and other items of cultural heritage. However, these studies involved concentrations of PM in ambient air greater than those typically observed in the U.S. (U.S. EPA, 2019a, section 13.4).

Building on the evidence available in the 2009 ISA, and as described in detail in the proposal (88 FR 5650, January 27, 2023) and in the 2019 ISA (U.S. EPA, 2019a, section 13.4), research has progressed on (1) the theoretical understanding of soiling of items of cultural heritage; (2) the quantification of degradation rates and further characterization of factors that influence damage of stone materials; (3) materials damage from PM components besides sulfate and black carbon and atmospheric gases besides SO_2; (4) methods for evaluating soiling of materials by PM mixtures; (5) PM-attributable damage to other materials, including glass and photovoltaic panels; (6) development of dose-response relationships for soiling of building materials; and (7) damage functions to quantify material decay as a function of pollutant type and load. While the evidence of PM-related materials effects has expanded somewhat since the completion of the 2009 ISA, there remains insufficient evidence to relate soiling or damage to specific PM levels in ambient air or to establish a quantitative relationship between PM and materials degradation. The recent evidence assessed in the 2019 ISA is generally similar to the evidence available in the 2009 ISA, including

[155] Radiative forcing (RF) for a given atmospheric constituent is defined as the perturbation in net radiative flux, at the tropopause (or the top of the atmosphere) caused by that constituent, in watts per square meter (Wm^{-2}), after allowing for temperatures in the stratosphere to adjust to the perturbation but holding all other climate responses constant, including surface and tropospheric temperatures (Fiore et al., 2015; Myhre et al., 2013). A positive forcing indicates net energy trapped in the Earth system and suggests warming of the Earth's surface, whereas a negative forcing indicates net loss of energy and suggests cooling (U.S. EPA, 2019a, section 13.3.2.2).

[156] As discussed in the 2019 ISA (U.S. EPA, 2019a, section 13.4.1), corrosion typically involves reactions of acidic PM (*i.e.,* acidic sulfate or nitrate) with material surfaces, but gases like SO_2 and nitric acid (HNO_3) also contribute. Because ''the impacts of gaseous and particulate N and S wet deposition cannot be clearly distinguished'' (U.S. EPA, 2019a, p. 13–1), the assessment of the evidence in the 2019 ISA considers the combined impacts.

associated limitations and uncertainties and a lack of evidence to inform quantitative relationships between PM and materials effects, therefore leading to similar conclusions about the PM-related effects on materials.

3. Summary of Air Quality and Quantitative Information

Beyond the consideration of the scientific evidence, as discussed in section V.A.2 above, quantitative analyses of PM air quality, when available, can also inform conclusions on the adequacy of the public welfare protection provided by the current secondary PM standards.

a. Visibility Effects

In the 2012 and 2020 reviews, quantitative analyses for PM-related visibility effects focused on daily visibility impairment, given the short-term nature of PM-related visibility effects. The evidence and information available in this reconsideration continues to provide support for the short-term (*i.e.,* hourly or daily) nature of PM-related visibility impairment. As such, the quantitative analyses presented in the 2022 PA continue to focus on daily visibility impairment and utilize a two-phase assessment approach for visibility impairment, consistent with the approaches taken in past reviews. First, the 2022 PA considers the appropriateness of the elements (indicator, averaging time, form, and level) of the visibility index for providing protection against PM-related visibility effects. Second, recent air quality was used to evaluate the relationship between the current secondary 24-hour $PM_{2.5}$ standard and the visibility index. The information available since the 2012 review includes an updated equation for estimating light extinction, summarized in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.1) and described in the 2019 ISA (U.S. EPA, 2019a, section 13.2.3.3), as well as more recent air monitoring data, that together allow for development of an updated assessment of PM-related visibility impairment in study locations in the U.S.

i. Target Level of Protection in Terms of a $PM_{2.5}$ Visibility Index

In evaluating the adequacy of the current secondary PM standards, the 2022 PA first evaluates the appropriateness of the elements (indicator, averaging time, form, and level) identified for a visibility index to protect against visibility effects. In previous reviews, the visibility index as set at a level of 30 dv, with estimated light extinction as the indicator, a 24-hour averaging time, and a 90th percentile form, averaged over three years.

With regard to an indicator for the visibility index, the 2022 PA recognizes the lack of availability of methods and an established network for directly measuring light extinction (U.S. EPA, 2022b, section 5.3.1.1). Therefore, consistent with previous reviews, the 2022 PA concludes that a visibility index based on estimates of light extinction by $PM_{2.5}$ components derived from an adjusted version of the original IMPROVE algorithm to be the most appropriate indicator for the visibility index in this reconsideration. As described in section 5.3.1.1 of the 2022 PA, the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity (U.S. EPA, 2022b, section 5.3.1.1).

With regard to averaging time, the 2022 PA notes that the evidence continues to provide support for the short-term nature of PM-related visibility effects. Given that there is no new information available regarding the time periods during which visibility impairment occurs or public preferences related to specific time periods for visibility impairment, the 2022 PA concludes that it is appropriate to continue to focus on daily visibility impairment. In so doing, the 2022 PA relies on analyses that were conducted in the 2012 review that showed relatively strong correlations between 24-hour and subdaily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction that indicated that a 24-hour averaging time is an appropriate surrogate for the subdaily time periods relevant for visual perception (U.S. EPA, 2011, Figures G–4 and G–5; Frank, 2012). These analyses continue to provide support for a 24-hour averaging time for the visibility index in this reconsideration. Consistent with previous reviews, the 2022 PA also notes that the 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance than a subdaily averaging time (85 FR 82740, December 18, 2020; 78 FR 3226, January 15, 2013).

With regard to the form for the visibility index, the available information continues to provide support for a 3-year average of annual 90th percentile values. Given that there is no new information to inform selection of an alternate form, as in previous reviews, the 2022 PA notes that the 3-year average form provides stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (85 FR 82741, December 18, 2020; 78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58). In so doing, the 2022 PA considers the evaluation in the 2010 Urban-Focused Visibility Assessment (UFVA) of three different statistical forms: 90th, 95th, and 98th percentiles (U.S. EPA, 2010b, Chapter 4).). In considering this evaluation of statistical forms from the 2010 UFVA, consistent with the 2011 PA, the 2022 PA notes that the Regional Haze Program targets the 20 percent most impaired days for visibility improvements in visual air quality in Federal Class I areas and that the median of the distribution of these 20 percent most impaired days would be the 90th percentile. The 2011 PA also noted that strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the visibility index would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Additionally, as in the 2011 PA, the 2022 PA recognizes that the available public preference studies do not address frequency of occurrence of different levels of visibility (U.S. EPA, 2022b, section 5.3.1.2). Therefore, the analyses and consideration for the form of a visibility index from the 2011 PA continue to provide support for a 90th percentile form, averaged across three years, in defining the characteristics of a visibility index in this reconsideration.

With regard to the level for the visibility index, the 2022 PA recognizes that there is an additional public preference study (Malm et al., 2019) available in this reconsideration. As noted above, however, this study differs from the previously available public preference studies in several ways, which makes it difficult to integrate this newly available study with the previously available studies. Most significantly, this study was evaluated public preferences for visibility in the Grand Canyon, perhaps the most notable Class I area in the country for visibility purposes. Therefore, the 2022 PA concludes that the Grand Canyon study is not directly comparable to the other available preferences studies and public preferences of visibility impairment in the Malm et al. (2019) study are not appropriate to consider in identifying a range of levels for the target level of protection against visibility impairment for this reconsideration of the secondary PM NAAQS.

Therefore, the 2022 PA continues to rely on the same studies [157] and the range of 20 to 30 dv identified from those studies in previous reviews. With regard to selecting the appropriate target level of protection for visibility impairment within this range, the 2022 PA notes that in previous reviews, a level at the upper end of the range (*i.e.,* 30 dv) was selected given the uncertainties and limitations associated with the public preference studies (U.S. EPA, 2022b, section 5.3.1.1). However, the 2022 PA also recognizes that (1) the degree of protection provided by a secondary PM NAAQS is not determined solely by any one element of the standard but by all elements (*i.e.,* indicator, averaging time, form, and level) being considered together, and (2) decisions regarding the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. As such, the Administrator may judge that a target level of protection below the upper end of the range (*i.e.,* less than 30 dv) is appropriate, depending on his public welfare policy judgments, which draw upon the available scientific evidence for PM-related visibility effects and on analyses of visibility impairment, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses.

In considering the available public preference studies, consistent with past reviews, the 2022 PA concludes that it is reasonable to consider a range of 20 to 30 dv for selecting a target level of protection, including a high value of 30 dv, a midpoint value of 25 dv, and a low value of 20 dv. A target level of protection at or in the upper end of the range would focus on the Washington, DC, preference study results (Abt Associates, 2001; Smith and Howell, 2009), which identified 30 dv as the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants. The public preferences of visibility impairment in the Washington, DC, study are likely to be generally representative of urban areas that do not have valued scenic elements (*e.g.,* mountains) in the distant background. This would be more representative of areas in the middle of the country and many areas in the eastern U.S., as well as possibly some areas in the western U.S.

A target level of protection in the middle of the range would be most closely associated with the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants in the Phoenix, AZ, study (BBC Research & Consulting, 2003), which was 24 dv. This study, while methodologically similar to the other public preference studies, included participants that were selected as a representative sample of the Phoenix area population [158] and used computer-generated images to depict specific uniform visibility impairment conditions. This study yielded the best results of the four public preference studies in terms of the least noisy preference results and the most representative selection of participants. Therefore, based on this study, the use of 25 dv to represent a midpoint within the range of target levels protection is well supported.

A target level of protection at or just above the lower end of the range would focus on the Denver, CO, study, but may not be as strongly supported as higher levels within the range (Ely et al., 1991). Older studies, such as those conducted in Denver, CO (Ely et al., 1991), and British Columbia, Canada (Pryor, 1996), used photographs that were taken at different times of the day and on different days to capture a range of light extinction levels needed for the preference studies. Compared to studies that used computer-generated images (*i.e.,* those in Phoenix, AZ, and Washington, DC) there was more variability in scene appearance in these older studies that could affect preference rating and includes uncertainties associated with using ambient measurements to represent sight path-averaged light extinction values rather than superimposing a computer-generated amount of haze onto the images. When using photographs, the intrinsic appearance of the scene can change due to meteorological conditions (*i.e.,* shadow patterns and cloud conditions) and spatial variations in ambient air quality that can result in ambient light extinction measurement not being representative of the sight-path-averaged light extinction. Computer-generated images, such as those generated with WinHaze, do not introduce such uncertainties, as the same base photograph is used (*i.e.,* there is no intrinsic change in scene appearance) and the modeled haze that is superimposed on the photograph is determined based on uniform light extinction throughout the scene.

In addition to differences in preferences that may arise from photographs versus computer-generated images, urban visibility preference may differ by location, and such differences may arise from differences in the cityscape scene that is depicted in the images. These differences are related to the perceived value of objects and scenes that are included in the image, as objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction is changed compared to similar scenes with objects at shorter distances. For example, a person (regardless of their location) evaluating visibility in an image with more scenic elements such as mountains or natural views may value better visibility conditions in these images compared to the same level of visibility impairment in an image that only depicts urban features such as buildings and roads. That is, if a person was shown the same level of visibility impairment in two images depicting different scenes—one with mountains in the background and urban features in the foreground and one with no mountains in the background and nearby buildings in the image without mountains in the distance—may find the amount of haze to be unacceptable in the image with the mountains in the distance because of a greater perceived value of viewing the mountains, while finding the amount of haze to be acceptable in the image with the buildings because of a lesser value of viewing the cityscape or an expectation that such urban areas may generally have higher levels of haze in general. This is consistent when comparing the differences between the Denver, CO, study results (which found the 50% acceptance criteria occurred at the best visual air quality levels among the four cities) and the Washington, DC, results (which found the 50% acceptability criteria occurred at the worst visual air quality levels among the four cities). These results may occur because the most prominent and picturesque feature of the cityscape of Denver is the visible snow-covered mountains in the distance, while the prominent and

[157] As noted above, the available public preference studies include those conducted in Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2001; Smith and Howell, 2009).

[158] The other preference studies did not include populations that were necessarily representative of the population in the area for which the images being judged. For example, in the Denver, CO, study, participants were from intact groups (*i.e.,* those who were meeting for other reasons) and were asked to provide a period of time during a regularly scheduled meeting to participate in the study (Ely et al., 1991). As another example, in the British Columbia, Canada, study, participants were recruited from undergraduate and graduate students enrolled in classes at the University of British Columbia's Department of Geography (Pryor, 1996).

picturesque features of the Washington, DC, cityscape are buildings relatively nearby without prominent and/or valued scenic features that are more distant. Given these variabilities in preferences it is unclear to what extent, the available evidence provides strong support for a target level of protection at the lower end of the range. Future studies that reduce sources of noisiness and uncertainty in the results could provide more information that would support selection of a target level of protection at or just above the lower end of the range.

Taken together, the 2022 PA concludes that available information continues to support a visibility index with estimated light extinction as the indicator, a 24-hour averaging time, and a 90th percentile form, averaged over three years, with a level within the range of 20 to 30 dv.

ii. Relationship Between the $PM_{2.5}$ Visibility Index and the Current Secondary 24-Hour $PM_{2.5}$ Standard

The 2022 PA presents quantitative analyses based on recent air quality that evaluate the relationship between recent air quality and calculated light extinction. As in previous reviews, these analyses explored this relationship as an estimate of visibility impairment in terms of the 24-hour $PM_{2.5}$ standard and the visibility index. Generally, the results of the updated analyses are similar to those based on the data available at the time of the 2012 and 2020 reviews (U.S. EPA, 2022b, section 5.3.1.2). As discussed in section V.C.1.a above, the 2022 PA concludes that the available evidence continues to support a visibility index with estimated light extinction as the indicator, a 24-hour averaging time, and a 90th percentile form, averaged over three years, with a level within the range of 20 to 30 dv. These analyses evaluate visibility impairment in the U.S. under recent air quality conditions, particularly those conditions that meet the current standards, and the relative influence of various factors on light extinction. Given the relationship of visibility with short-term PM, we focus particularly on the short-term PM standards.[159] Compared to the 2012 review, updated analyses incorporate several refinements, including (1) the evaluation of three versions of the IMPROVE equation to calculate light extinction (U.S. EPA, 2022b, Appendix D, Equations D–1 through D–3) in order to better understand the influence of variability in equation inputs; [160] (2) the use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the 2012 review (U.S. EPA, 2022b, section 5.3.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction (U.S. EPA, 2022b, section 5.3.1.2, Appendix D). The analyses in the reconsideration are updated from the 2012 and 2020 reviews and include 60 monitoring sites that measure $PM_{2.5}$ and PM_{10} and are geographically distributed across the U.S. in both urban and rural areas (U.S. EPA, 2022b, Appendix D, Figure D–1).

When light extinction was calculated using the revised IMPROVE equation, in areas that meet the current 24-hour $PM_{2.5}$ standard for the 2017–2019 time period, all sites have light extinction estimates at or below 26 dv (U.S. EPA, 2022b, Figure 5–3). For the four locations that exceed the current 24-hour $PM_{2.5}$ standard, light extinction estimates range from 22 dv to 27 dv (U.S. EPA, 2022b, Figure 5–3). These findings are consistent with the findings of the analyses using the same IMPROVE equation in the 2012 review with data from 102 sites with data from 2008–2010 and in the 2020 review with data from 67 sites with data from 2015–2017. The analyses presented in the 2022 PA indicate similar findings to those from the analyses in the 2012 and 2020 reviews, *i.e.,* the updated quantitative analysis shows that the 3-year visibility metric was no higher than 30 dv [161] at sites meeting the current secondary PM standards, and at most such sites the 3-year visibility index values are much lower (*e.g.,* an average of 20 dv across the 60 sites).[162]

When light extinction was calculated using the revised IMPROVE equation,[163] the resulting 3-year visibility metrics are nearly identical to light extinction estimates calculated using the original IMPROVE equation (U.S. EPA, 2022b, Figure 5–4), but some sites are just slightly higher. Using the revised IMPROVE equation, for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is at or below 26 dv. For the four locations that exceed the current 24-hour $PM_{2.5}$ standard, light extinction estimates range from 22 dv to 29 dv (U.S. EPA, 2022b, Figure 5–4). These results are similar to those for light extinction calculated using the original IMPROVE equation,[164] and those from previous reviews.

When light extinction was calculated using the refined equation from Lowenthal and Kumar (2016), the resulting 3-year visibility metrics are slightly higher at all sites compared to light extinction estimates calculated using the original IMPROVE equation (U.S. EPA, 2022b, Figure 5–5).[165] These higher estimates are to be expected, given the higher OC multiplier included in the IMPROVE equation from Lowenthal and Kumar (2016), which reflects the use of data from remote areas with higher concentrations of organic PM when validating the equation. As such, it is important to note that the Lowenthal and Kumar (2016) version of the equation may overestimate light extinction in non-remote areas, including the urban areas in the updated analyses in this reconsideration.

Nevertheless, when light extinction is calculated using the Lowenthal and

[159] The analyses presented in the 2022 PA focus on the visibility index and the current secondary 24-hour $PM_{2.5}$ standard with a level of 35 $\mu g/m^3$. However, we recognize that all three secondary PM standards influence the PM concentrations associated with the air quality distribution. As noted in section V.A.1 above, the current secondary PM standards include the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, the annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$, and the 24-hour PM_{10} standard, with its level of 150 $\mu g/m^3$. With regard to the annual $PM_{2.5}$ standard, we note that all 60 areas included in the analyses meet the current secondary annual PM standard (U.S. EPA, 2022b, Table D–7).

[160] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for subdaily visibility impairment estimates. As detailed in the 2022 PA, there are uncertainties associated with the precision and bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2022b, p. 2–18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2022b, p. 2–21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with subdaily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than subdaily information.

[161] A 3-year visibility metric with a level of 30 dv would be at the upper end of the range of levels identified from the public preference studies.

[162] When light extinction is calculated using the original IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 58 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D–3).

[163] As described in more detail in the 2022 PA, the revised IMPROVE equation divides PM components into smaller and larger sizes of particles in $PM_{2.5}$, with separate mass scattering efficiencies and hygroscopic growth functions for each size category (U.S. EPA, 2022b, section 5.3.1.1).

[164] When light extinction is calculated using the revised IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 56 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D–3).

[165] When light extinction is calculated using the Lowenthal and Kumar IMPROVE equation, 59 sites have 3-year visibility metrics below 30 dv, 45 sites are at or below 25 dv, and 15 sites are at or below 20 dv. The one site with a 3-year visibility metric of 32 dv exceeds the secondary 24-hour $PM_{2.5}$ standard, with a design value of 56 $\mu g/m^3$ (see U.S. EPA, 2022b, Appendix D, Table D–3).

Kumar (2016) equation for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is generally at or below 28 dv. For those sites that exceed the current 24-hour $PM_{2.5}$ standard, three of these sites have a 3-year visibility metric ranging between 26 dv and 30 dv, while one site in Fresno, California that exceeds the current 24-hour $PM_{2.5}$ standard and has a 3-year visibility index value of 32 dv (compared to 29 dv when light extinction is calculated with the original IMPROVE equation) (see U.S. EPA, 2022b, Appendix D, Table D–3). At this site, it is likely that the 3-year visibility metric using the Lowenthal and Kumar (2016) equation would be below 30 dv if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained.

In considering visibility impairment under recent air quality conditions, the 2022 PA recognizes that the differences in the inputs to equations estimating light extinction can influence the resulting values. For example, given the varying chemical composition of emissions from different sources, the 2.1 multiplier for converting OC to organic matter (OM) in the Lowenthal and Kumar (2016) equation may not be appropriate for all source types. At the time of the 2012 review, the EPA judged that a 1.6 multiplier was more appropriate, for the purposes of estimating visibility index at sites across the U.S., than the 1.4 or 1.8 multipliers used in the original and revised IMPROVE equations, respectively. A multiplier of 1.8 or 2.1 would account for the more aged and oxygenated organic PM that tends to be found in more remote regions than in urban regions, whereas a multiplier of 1.4 may underestimate the contribution of organic PM found in remote regions when estimating light extinction (78 FR 3206, January 15, 2013; U.S. EPA, 2012, p. IV–5). The available scientific information and results of the air quality analyses indicate that it may be appropriate to select inputs to the IMPROVE equation (*e.g.,* the multiplier for OC to OM) on a regional basis rather than a national basis when calculating light extinction. This is especially true when comparing sites with localized PM sources (such as sites in urban or industrial areas) to sites with PM derived largely from biogenic precursor emissions (that contribute to widespread secondary organic aerosol formation), such as those in the southeastern U.S. The 2022 PA notes, however, that conditions involving PM from such different sources have not been well studied in the context of applying a multiplier to estimate light extinction, contributing uncertainty to estimates of light extinction for such conditions.

At the time of the 2012 review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (77 FR 38980, June 29, 2012). Data available at the time of the 2012 review suggested that, generally, $PM_{10–2.5}$ was a minor contributor to visibility impairment most of the time (U.S. EPA, 2010b) although the coarse fraction may be a major contributor in some areas in the desert southwestern region of the U.S. Moreover, at the time of the 2012 review, there were few data available from $PM_{10–2.5}$ monitors to quantify the contribution of coarse PM to calculated light extinction. Since that time, an expansion in $PM_{10–2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction with both $PM_{2.5}$ and $PM_{10–2.5}$ concentrations included as inputs in the equations. The analysis in the 2020 PA addressed light extinction at 20 of the 67 $PM_{2.5}$ sites where collocated $PM_{10–2.5}$ monitoring data were available. Since that time, $PM_{10–2.5}$ monitoring data are available at more locations and the analyses presented in the 2022 PA include those for light extinction estimated with coarse and fine PM at all 60 sites. Generally, the contribution of the coarse fraction to light extinction at these sites is minimal, contributing less than 1 dv to the 3-year visibility metric (U.S. EPA, 2020b, section 5.2.1.2). However, the 2022 PA notes that in the updated quantitative analyses, only a few sites were in locations that would be expected to have high concentrations of coarse PM, such as the Southwest. These results are consistent with those in the analyses in the 2019 ISA, which found that mass scattering from $PM_{10-2.5}$ was relatively small (less than 10%) in the eastern and northwestern U.S., whereas mass scattering was much larger in the Southwest (more than 20%) particularly in southern Arizona and New Mexico (U.S. EPA, 2019a, section 13.2.4.1, p. 13–36).

Overall, the findings of these updated quantitative analyses are generally consistent with those in the 2012 and 2020 reviews. The 3-year visibility metric was generally below 26 dv in most areas that meet the current 24-hour $PM_{2.5}$ standard. Small differences in the 3-year visibility metric were observed between the variations of the IMPROVE equation, which may suggest that it may be more appropriate to use one version over another in different regions of the U.S. based on PM characteristics such as particle size and composition to more accurately estimate light extinction.

b. Non-Visibility Effects

Consistent with the evidence available at the time of the 2012 and 2020 reviews, and as described in detail in the 2022 PA (U.S. EPA, 2022b, section 5.3.2.2), the data remain insufficient to conduct quantitative analyses for PM effects on climate and materials. For PM-related climate effects, as explained in more detail in the proposal (88 FR 5654, January 27, 2023), our understanding of PM-related climate effects is still limited by significant key uncertainties. The recently available evidence does not appreciably improve our understanding of the spatial and temporal heterogeneity of PM components that contribute to climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Significant uncertainties also persist related to quantifying the contributions of PM and PM components to the direct and indirect effects on climate forcing, such as changes to the pattern of rainfall, changes to wind patterns, and effects on vertical mixing in the atmosphere (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Additionally, while improvements have been made to climate models since the completion of the 2009 ISA, the models continue to exhibit variability in estimates of the PM-related climate effects on regional scales (*e.g.,* ~100 km) compared to simulations at the global scale (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). While our understanding of climate forcing on a global scale is somewhat expanded since the 2012 review, significant limitations remain to quantifying potential adverse PM-related climate effects in the U.S. and how they would vary in response to incremental changes in PM concentrations across the U.S. As such, while recent research is available on climate forcing on a global scale, the remaining limitations and uncertainties are significant, and the recent global scale research does not translate directly for use at regional spatial scales. Therefore, the evidence does not provide a clear understanding at the necessary spatial scales for quantifying the relationship between PM mass in ambient air and the associated climate-related effects in the U.S. that would be necessary to evaluate or consider a level of air quality to protect against such effects and for informing consideration of a national PM standard on climate in this reconsideration (U.S. EPA, 2022b, section 5.3.2.2.1; U.S. EPA, 2019a, section 13.3).

For PM-related materials effects, as explained in more detail in the 2022 PA (U.S. EPA, 2022b, section 5.3.2.2), the available evidence has been somewhat expanded to include additional information about the soiling process and the types of materials impacted by PM. This evidence provides some limited information to inform dose-response relationships and damage functions associated with PM, although most of these studies were conducted outside of the U.S. where PM concentrations in ambient air are typically above those observed in the U.S. (U.S. EPA, 2022b, section 5.3.2.1.2; U.S. EPA, 2019a, section 13.4). The evidence on materials effects characterized in the 2019 ISA also includes studies examining effects of PM on the energy efficiency of solar panels and passive cooling building materials, although the evidence remains insufficient to establish quantitative relationships between PM in ambient air and these or other materials effects (U.S. EPA, 2022b, section 5.3.2.1.2). While the available evidence assessed in the 2019 ISA is somewhat expanded since the time of the 2012 review, quantitative relationships have not been established for PM-related soiling and corrosion and frequency of cleaning or repair that further the understanding of the public welfare implications of materials effects (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4). Therefore, there is insufficient information to inform quantitative analyses assessing materials effects to inform consideration of a national PM standard on materials in this reconsideration (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4).

B. Conclusions on the Secondary PM Standards

In drawing conclusions on the adequacy of the current secondary PM standards, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the 2020 decision and reflects upon the body of information and evidence available in this reconsideration. In so doing, the Administrator has taken into account both evidence-based and quantitative information-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from studies evaluating welfare effects related to visibility, climate, and materials associated with PM in ambient air as discussed in the 2022 PA (summarized in sections V.B and V.D.2 of the proposal, section V.A.2 above). The quantitative information-based considerations draw from the results of the quantitative analyses of visibility impairment presented in the 2022 PA (as summarized in section V.C of the proposal and V.A.3 above) and consideration of these results in the 2022 PA.

Consideration of the scientific evidence and quantitative information in the 2022 PA and by the Administrator is framed by consideration of a series of policy-relevant questions. Section V.B.2 below summarizes the rationale for the Administrators proposed decision, drawing from section V.D.3 of the proposal. The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections V.B.1 and V.B.3, respectively. The Administrator's conclusions in this reconsideration regarding the adequacy of the secondary PM standards and whether any revisions are appropriate are described in section V.D.4.

1. CASAC Advice

In comments on the 2019 draft PA, the CASAC concurred with the staff's overall preliminary conclusions that it is appropriate to consider retaining the current secondary standards without revision (Cox, 2019b). The CASAC ''finds much of the information . . . on visibility and materials effects of $PM_{2.5}$ to be useful, while recognizing that uncertainties and controversies remain about the best ways to evaluate these effects'' (Cox, 2019b, p. 13 of consensus responses). Regarding climate, while the CASAC agreed that research on PM-related effects has expanded since the 2012 review, it also concluded that ''there are still significant uncertainties associated with the accurate measurement of PM to the direct and indirect effects of PM on climate'' (Cox, 2019b, pp. 13–14 of consensus responses). The committee recommended that the EPA summarize the ''current scientific knowledge and quantitative modeling results for effects of reducing $PM_{2.5}$'' on several climate-related outcomes (Cox, 2019b, p. 14 of consensus responses), while also recognizing that ''it is appropriate to acknowledge uncertainties in climate change impacts and resulting welfare impacts in the United States of reductions in $PM_{2.5}$ levels'' (Cox, 2019b, p. 14 of consensus responses). When considering the overall body of scientific evidence and technical information for PM-related effects on visibility, climate, and materials, the CASAC agreed with the EPA's preliminary conclusions in the 2019 draft PA, stating that ''the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained'' (Cox, 2019b, p. 3 of letter).

In this reconsideration, the CASAC provided its advice regarding the current secondary PM standards in the context of its review of the 2021 draft PA (Sheppard, 2022a). In its comments on the 2021 draft PA, the CASAC first recognized that the scientific evidence is sufficient to support a causal relationship between PM and visibility effects, climate effects and materials effects.

With regard to visibility effects, the CASAC recognized that the identification of a target level of protection for the visibility index is based on a limited number of studies and suggested that ''additional region- and view-specific visibility preference studies and data analyses are needed to support a more refined visibility target'' (Sheppard, 2022a, p. 21 of consensus responses). While the CASAC did not recommend revising either the target level of protection for the visibility index or the level of the current 24-hour $PM_{2.5}$ standard, they did state that a visibility index of 30 deciviews ''needs to be justified'' and ''[i]f a value of 20–25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25–35 $\mu g/m^3$ should be considered'' (Sheppard, 2022a, p. 21 of consensus responses).

The CASAC also recognized the limited availability of monitoring methods and networks for directly measuring light extinction. As such, they suggest that ''[a] more extensive technical evaluation of the alternatives for visibility indicators and practical measurement methods (including the necessity for a visibility FRM) is need for future reviews'' (Sheppard, 2022a, p. 22 of consensus letter). The majority of the CASAC ''recommend[ed] that an FRM for a directly measured $PM_{2.5}$ light extinction indicator be developed'' to inform the consideration of the protection afforded by the secondary PM standards against visibility impairment, the minority of the CASAC ''believe that a light extinction FRM is not necessary to set a secondary standard protective of visibility'' (Sheppard, 2022a, p. 22 of consensus responses).

With regard to climate, the CASAC noted that ''there is a causal relationship between PM and climate change, but large uncertainties remain'' and recommended additional research (Sheppard, 2022a, p. 22 of consensus responses). With respect to materials damage, the CASAC noted that ''[q]uantitative information on the relationship between PM and material damage is lacking'' and suggested some additional studies and research approaches that could provide additional information on the effects of PM on materials and the quantitative assessment of the relationship between materials effects and PM in ambient air (Sheppard, 2022a, p. 23 of consensus responses).

2. Basis for the Proposed Decision

In reaching his proposed conclusions, the Administrator first recognized that, consistent with the scope of this reconsideration, his decision in this reconsideration will be focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials. He then considered the assessment of the current evidence and conclusions reached in the 2019 ISA and ISA Supplement; the currently available quantitative information, including associated limitations and uncertainties, described in detail and characterized in the 2022 PA; considerations and staff conclusions and associated rationales presented in the 2022 PA; and the advice and recommendations from the CASAC (88 FR 5655, January 27, 2023).

With respect to visibility, the Administrator noted the longstanding body of evidence that demonstrates a causal relationship between ambient PM and effects on visibility (U.S. EPA, 2019a, section 13.2). and that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. Therefore, as in previous reviews, he considered the degree to which the current secondary standards protect against PM-related visibility impairment. In so doing, and consistent with previous reviews, the Administrator considered the protection provided by the current secondary standards against PM-related visibility impairment in conjunction with the Regional Haze Program [166] for protecting visibility in Class I areas,[167] which together would be expected to achieve appropriate visual air quality across all areas (88 FR 5658, January 27, 2023). The Administrator proposed to conclude that addressing visibility impairment in Class I areas is beyond the scope of the secondary PM NAAQS and that setting the secondary PM NAAQS at a level that would remedy visibility impairment in Class I areas would result in standards that are more stringent than is requisite.

In further considering what standards are requisite to protect against adverse public welfare effects from visibility impairment, the Administrator adopted an approach consistent with the approach used in previous reviews (88 FR 5645, January 27, 2023). That is, he first identified an appropriate target level of protection in terms of a PM visibility index that accounts for the factors that influence the relationship between particles in the ambient air and visibility (*i.e.,* size fraction, species composition, and relative humidity). He then considered air quality analyses examining the relationship between this PM visibility index and the current secondary 24-hour $PM_{2.5}$ standard in locations meeting the current 24-hour $PM_{2.5}$ and PM_{10} standards (U.S. EPA, 2022b, section 5.3.1.2; 88 FR 5650, January 27, 2023).

To identify a target level of protection, the Administrator first considered the characteristics of the visibility index and defines its elements (indicator, averaging time, form, and level). With regard to the indicator for the visibility index, the Administrator recognized that there is a lack of availability of methods and an established network for directly measuring light extinction, consistent with the conclusions reached in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.1) and with the CASAC's recommendation for additional research on direct measurement methods for light extinction in their review of the 2021 draft PA (Sheppard, 2022a, p. 22 of consensus responses). Consistent with the approaches used in reaching decisions in 2012 and 2020, given the lack of such monitoring data, the Administrator preliminarily judged that estimated light extinction, as calculated using one or more versions of the IMPROVE algorithms, continues to be the most appropriate indicator for the visibility index in this reconsideration (88 FR 5659, January 27, 2023).

In further defining the characteristics of a visibility index based on estimates of light extinction, the Administrator considered the appropriate averaging time, form, and level of the index. With regard to the averaging time and form, the Administrator noted that in previous reviews, a 24-hour averaging time was selected and the form was defined as the 3-year average of annual 90th percentile values. The Administrator recognized that the evidence available in this reconsideration and described in the 2022 PA continue to provide support for the short-term nature of PM-related visibility effects. Considering the available analyses of 24-hour and subdaily $PM_{2.5}$ light extinction, and noting that the CASAC did not provide advice or recommendations with regard to the averaging time of the visibility index, the Administrator preliminarily judged that the 24-hour averaging time continues to be appropriate for the visibility index (88 FR 5659, January 27, 2023).

With regard to the form of the visibility index, the Administrator noted that, consistent with the approach taken in other NAAQS, including the current secondary 24-hour $PM_{2.5}$ NAAQS, a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Using a 3-year average provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (88 FR 5659, January 27, 2023). In considering the percentile that would be appropriate with the 3-year average, the Administrator first noted that the Regional Haze Program targets the 20% most impaired days for improvements in visual air quality in Class I areas.[168] Based on analyses examining 90th, 95th, and 98th percentile forms, the Administrator preliminarily judged that a focus similar to the Regional Haze Program focused on improving the 20% most impaired days suggest that the 90th percentile, which represents the median of the 20% most impaired days, such that 90% of days have visual air quality that is at or below the target level of protection of the visibility

[166] The Regional Haze Program was established by Congress specifically to achieve ''the prevention of any future, and the remedying of existing, impairment of visibility in mandatory Class I areas, which impairment results from man-made air pollution,'' and that Congress established a long-term program to achieve that goal (CAA section 169A).

[167] In adopting section 169A, Congress set a goal of eliminating anthropogenic visibility impairment at Class I areas, as well as a framework for achieving that goal which extends well beyond the planning process and timeframe for attaining secondary NAAQS. Thus, the Regional Haze Program will continue to contribute to reductions in visibility impairment in Class I areas.

[168] As noted above, the Administrator viewed the Regional Haze Program as a complement to the secondary PM NAAQS, and thus took into consideration its approach to improving visibility in considering how to address visibility outside of Class I areas.

index, would be reasonably expected to lead to improvements in visual air quality for the 20% most impaired days (88 FR 5659, January 27, 2023). In the analyses of percentiles, the results suggest that a higher percentile value could have the effect of limiting the occurrence of days with peak PM-related light extinction in areas outside of Federal Class I areas to a greater degree. However, the Administrator preliminarily concluded that it is appropriate to balance concerns about focusing on the group of most impaired days with concerns about focusing on the days with peak visibility impairment. Additionally, the Administrator noted that the CASAC did not provide advice or recommendations related to the form of the visibility index. Therefore, the Administrator preliminarily judged that it remains appropriate to define a visibility index in terms of a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values (88 FR 5659, January 27, 2023).

With regard to the level of the visibility index, the Administrator first noted that the scientific evidence that is available to inform the level of the visibility index is largely the same as in previous reviews, and continues to provide support for a level within the range of 20 to 30 dv (88 FR 5659–5660, January 27, 2023). The Administrator recognized that significant uncertainties and limitations remained, in particular those related to the public preference studies, including methodological differences between the studies, and that the available studies may not capture the full range of visibility preferences in the U.S. population (88 FR 5659–5660, January 27, 2023). The Administrator also noted that, in their review of the 2021 draft PA, the CASAC recognized that a judgment regarding the appropriate target level of protection for the visibility index is based on a limited number of visibility preference studies, with studies conducted in the western U.S. reporting public preferences for visibility impairment associated with the lower end of the range of levels, while studies conducted in the eastern U.S. reporting public preferences associated with the upper end of the range (Sheppard, 2022a, p. 21 of consensus responses). The Administrator noted that there have long been significant questions about how to set a national standard for visibility that is not overprotective for some areas of the U.S. In establishing the Regional Haze Program to improve visibility in Class I areas, Congress noted that ''as a matter of equity, the national ambient air quality standards cannot be revised to adequately protect visibility in all areas of the country.'' H.R. Rep. 95–294 at 205. Thus, in reaching his proposed conclusion, the Administrator recognized that there are substantial uncertainties and limitations in the public preference studies that should be considered when selecting a target level of protection for the visibility index and took the uncertainties and variability inherent in the public preference studies into account. In so doing, the Administrator first preliminarily judged that, consistent with similar judgments in past reviews, it is appropriate to recognize that the secondary 24-hour $PM_{2.5}$ standard is intended to address visibility impairment across a wide range of regions and circumstances, and that the current standard works in conjunction with the Regional Haze Program to improve visibility, and therefore, it is appropriate to establish a target level of protection based on the upper end of the range of levels. In considering the information available in this reconsideration and the CASAC's advice, the Administrator proposed to conclude that the protection provided by a visibility index based on estimated light extinction, a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv (the upper end of the range of levels) would be requisite to protect public welfare with regard to visibility impairment (88 FR 5660, January 27, 2023).

In preliminarily concluding that it remains appropriate in this reconsideration to define the target level of protection in terms of a visibility index based on estimated light extinction as described above (*i.e.,* with a 24-hour averaging time; a 3-year, 90th percentile form; and a level of 30 dv), the Administrator next considered the degree of protection from visibility impairment afforded by the existing secondary standards. He considered the updated analyses of PM-related visibility impairment presented in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.2), which reflect several improvements over the analyses conducted in the 2012 review. Specifically, the updated analyses examine multiple versions of the IMPROVE algorithm, including the version incorporating revisions since the 2012 review (section V.B.1.a), which provides an improved understanding of how variation in equation inputs impacts calculated light extinction (U.S. EPA, 2022b, Appendix D). In addition, unlike the analyses in the 2012 review and the 2020 PA, all of the sites included in the analyses had $PM_{10–2.5}$ data available, which allows for better characterization of the influence of the coarse fraction on light extinction (U.S. EPA, 2022b, section 5.3.1.2).

The Administrator noted that the results of these updated analyses are consistent with the results from the 2012 and 2020 reviews (88 FR 5660, January 27, 2023). Regardless of the IMPROVE equation used, these analyses demonstrate that the 3-year visibility metric is at or below 28 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard (section V.C.1.b). Given the results of these analyses, the Administrator preliminarily concluded that the updated scientific evidence and technical information support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment. While the inclusion of the coarse fraction had a relatively modest impact on calculated light extinction in the analyses presented in the 2022 PA, he nevertheless recognized the continued importance of the PM_{10} standard given the potential for larger impacts in locations with higher coarse particle concentrations, such as in the southwestern U.S., for which only a few sites met the criteria for inclusion in the analyses in the 2022 PA (U.S. EPA, 2019a, section 13.2.4.1; U.S. EPA, 2022b, section 5.3.1.2).

With regard to the adequacy of the secondary 24-hour $PM_{2.5}$ standard, the Administrator noted that the CASAC stated that ''[i]f a value of 20–25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25–35 $\mu g/m^3$ should be considered'' (Sheppard, 2022a, p. 21 of consensus responses). The Administrator recognized that the CASAC recommended that the Administrator provide additional justification for a visibility index target of 30 dv but did not specifically recommend that he choose an alternative level for the visibility index. The Administrator considered the CASAC's advice, together with the available scientific evidence and quantitative information, in reaching his proposed conclusions. He recognized conclusions regarding the appropriate weight to place on the scientific and technical information examining PM-related visibility impairment including how to consider the range and magnitude of uncertainties inherent in that information is a public welfare policy judgment left to the Administrator. As such, the Administrator noted his conclusion on

the appropriate visibility index (*i.e.,* with a 24-hour averaging time; a 3-year, 90th percentile form; and a level of 30 dv) and his conclusions regarding the quantitative analyses of the relationship between the visibility index and the current secondary 24-hour $PM_{2.5}$ standard. In so doing, he proposed to conclude that the current secondary standards provide requisite protection against PM-related visibility effects (88 FR 5661, January 27, 2023).

In reaching his proposed conclusions, the Administrator also recognized that the available evidence on visibility impairment generally reflects a continuum and that the public preference studies did not identify a specific level of visibility impairment that would be perceived as ''acceptable'' or ''unacceptable'' across the whole U.S. population. However, he noted that a judgment regarding the appropriate target level of protection would take into consideration the appropriate weight to place on the individual public preference studies. In so doing, he noted that placing more weight on the public preference study from Washington, DC, could provide support for a target level of protection at or near 30 dv, whereas placing more weight on the public preference study performed in the Phoenix, AZ, study could provide support for a target level of protection below 30 dv and down to 25 dv. While the Administrator noted that, in their review of the 2021 draft PA, the CASAC did not recommend revising the level of the current 24-hour $PM_{2.5}$ standard, the Administrator recognized that they did recommend greater justification for a target level of protection of 30 dv, and noted that if a target level of protection of 20–25 dv was identified, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25–35 $\mu g/m^3$ should be considered (Sheppard, 2022a, p. 21 of consensus responses). For these reasons, the Administrator solicited comment on his proposed decision to retain the current secondary 24-hour $PM_{2.5}$ standard, as well as the appropriateness of a target level of protection for visibility below 30 dv and as low as 25 dv, and on revising the level of the current secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$.

With respect to climate effects, the Administrator recognized that a number of improvements and refinements have been made to climate models since the time of the 2012 review. However, despite continuing research and the strong evidence supporting a causal relationship with climate effects (U.S. EPA, 2019a, section 13.3.9), the Administrator noted that there are still significant limitations in quantifying the contributions of the direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). He also recognized that models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km), compared to simulations at the global scale (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). As noted above, the CASAC recognized a causal relationship between PM and climate effects but also the large uncertainties associated with quantitatively assessing such effects, particularly on a national level in the context of a U.S.-based standard. These uncertainties led the Administrator to preliminarily conclude that the scientific information available in this reconsideration remains insufficient to quantify, with confidence, the impacts of ambient PM on climate in the U.S. (U.S. EPA, 2022b, section 5.3.2.2.1) and that there is insufficient information at this time to revise the current secondary PM standards or to promulgate a distinct secondary standard to address PM-related climate effects (88 FR 5661, January 27, 2023).

With respect to materials effects, the Administrator noted that the available evidence continues to support the conclusion that there is a causal relationship with PM deposition (U.S. EPA, 2019a, section 13.4). He recognized that deposition of particles in the fine or coarse fractions can result in physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the effects of natural weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. While some recent evidence on materials effects of PM is available in the 2019 ISA, the Administrator noted that this evidence is primarily from studies conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2019a, section 13.4). The CASAC also noted the lack of quantitative information relating PM and material effects. Given the limited amount of information on the quantitative relationships between PM and materials effects in the U.S., and uncertainties in the degree to which those effects could be adverse to the public welfare, the Administrator preliminarily judged that the scientific information available in this reconsideration remains insufficient to quantify, with confidence, the public welfare impacts of ambient PM on materials and that there is insufficient information at this time to revise the current secondary PM standards or to promulgate a distinct secondary standard to address PM-related materials effects (88 FR 5661, January 27, 2023).

Taken together, the Administrator proposed to conclude that the scientific and technical information for PM-related visibility impairment, climate impacts, and materials effects, with its attendant uncertainties and limitations, supports the current level of protection provided by the secondary PM standards as being requisite to protect against known and anticipated adverse effects on public welfare. For visibility impairment, this proposed conclusion reflected his consideration of the evidence for PM-related light extinction, together with his consideration of updated analyses of the protection provided by the current secondary $PM_{2.5}$ and PM_{10} standards. For climate and materials effects, this conclusion reflected his preliminary judgment that, although it remains important to maintain secondary $PM_{2.5}$ and PM_{10} standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, it is generally appropriate not to change the existing secondary standards at this time and that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate and materials effects at this time. As such, the Administrator recognized that current suite of secondary standards (*i.e.,* the 24-hour $PM_{2.5}$, 24-hour PM_{10}, and annual $PM_{2.5}$ standards) together provide such control for both fine and coarse particles and long- and short-term visibility and non-visibility (*e.g.,* climate and materials) [169] effects related to PM in ambient air. His proposed conclusions on the secondary standards were consistent with advice from the CASAC, which noted substantial uncertainties remain in the scientific evidence for climate and materials effects. Thus, based on his consideration of the evidence and analyses for PM-related welfare effects, as described above, and his consideration of CASAC advice on the secondary standards, the Administrator proposed not to change those standards (*i.e.,* the current 24-hour and annual $PM_{2.5}$ standards, 24-hour PM_{10} standard) at this time (88 FR 5662, January 27, 2023).

[169] As noted earlier, other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few were specific to the secondary PM standards. Of those commenters who did provide comments on the secondary PM standards, the majority support the Administrator's proposed decision to retain the current standards. Some commenters disagree with the Administrator's proposed conclusion to retain the current secondary standards, primarily focusing their comments on the need for a revised standard to protect against visibility impairment. In addition to the comments addressed in this notice, the EPA has prepared a Response to Comments document that addresses other specific comments related to setting the secondary PM standards. This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*).

We first note that some commenters raise questions about the protection provided by the secondary PM standards for ecological effects (*e.g.,* effects on ecosystems, ecosystem services, or species). However, consistent with the 2016 IRP and as described in the proposal (88 FR 5643, January 27, 2023), other welfare effects of PM, such as the ecological effects identified by commenters, are being considered as part of the separate, ongoing review of the secondary standards for oxides of sulfur, oxides of nitrogen and PM, and thus, those comments are beyond the scope of this action.

Of the comments addressing the proposed decision for the secondary PM standards, many of the commenters support the Administrator's proposed decision to retain the current secondary PM standards, without revision. This group includes industries and industry groups and State and local governments and organizations. All of these commenters generally note their agreement with the rationale provided in the proposal, with a focus on the strength of the available scientific evidence for PM-related welfare effects. Most also recognize that the scientific evidence and quantitative information available in this reconsideration have not substantially altered our previous understanding of PM-related effects on non-ecological welfare effects (*i.e.,* visibility, climate, and materials) and do not call into question the adequacy of the current secondary standards. They find the proposed decision not to change the standards at this time to be well supported and a reasonable exercise of the Administrator's public welfare policy judgment under the CAA. The EPA agrees with these comments regarding the adequacy of the current secondary PM standards and the lack of support for revision of these standards at this time.

The EPA received relatively few comments on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate effects. Several commenters agree that the available scientific evidence provides support for the 2019 conclusion that there is a causal relationship between PM and climate effects, and the commenters also agree with the EPA that the currently available information is not sufficient for supporting quantitative analyses for the climate effects of PM in ambient air. These commenters support the Administrator's proposed decision not to set a distinct standard for climate.

There were also very few commenters who commented on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related materials effects. As with comments on climate effects, commenters generally agree with the EPA that the evidence is not sufficient to support quantitative analyses for PM-related materials effects. However, some commenters contend that EPA failed to explain in the proposal how the current standard is appropriate to protect materials from the effects of PM. These commenters disagree with the EPA's conclusion that quantitative relationships have not been established for PM-related soiling and corrosion and frequency of cleaning or repair of materials, and cite to several studies conducted outside the U.S. that they contend that the EPA should consider since the same materials are present in the U.S. They further contend that, in discussing the available scientific evidence in the 2019 ISA for studies conducted outside of the U.S., the EPA did not provide references to these studies and, therefore, the public is unable to comment on these studies. They further State that EPA failed to consider the following information: (1) Recent work related to soiling of photovoltaic modules and other surfaces, and; (2) damage and degradation resulting from oxidant concentrations and solar radiation for a number of materials, including polymeric materials, plastic, paint, and rubber. These commenters further assert that the EPA failed to propose a standard that provides requisite protection against materials effects attributable to PM.

As an initial matter, we note that the commenters submitted the same comments related to materials effects during the 2020 review. Consistent with our response in the 2020 notice of final rulemaking (85 FR 82737, December 18, 2020), we disagree with the commenters that the EPA failed to consider the relevant scientific information about materials effects available in this reconsideration. The 2019 ISA considered and included studies related to materials effects of PM, including studies conducted in and outside of the U.S., on newly studied materials including photovoltaic modules that were published prior to the cutoff date for the literature search.[170] These include the Besson et al. (2017) study referenced by the commenters (U.S. EPA, 2019a, section 13.4.2). The Grøntoft et al. (2019) study referenced by the same commenters was published after the cutoff date for the literature search for the 2019 ISA. However, the EPA provisionally considered new studies in responding to comments in the 2020 review, including the new studies highlighted by the commenters in their comments on the 2020 notice of proposed rulemaking, in the context of the findings of the 2019 ISA (see Appendix in U.S. EPA, 2020a).[171] Based on the provisional consideration, the EPA concluded in the 2020 review that the new studies are not sufficient to alter the conclusions reached in the 2019 ISA regarding PM and materials effects. For example, the Grøntoft et al. (2019) study was based on European air pollution which as the EPA has noted has higher concentrations (as well as diversity in sources, such as light duty diesel engines) compared to the U.S.. Thus, the EPA did not find it necessary or appropriate to reopen the air quality criteria to consider this study because it would not have been an adequate basis on which to set a NAAQS. As discussed in section I, when the EPA decided to reconsider the standards, it also decided to reopen the air quality criteria to a limited degree, based on its judgment that certain new studies were likely to be useful in reconsidering the standards.

[170] As noted earlier in section V, the 2019 ISA ''identified and evaluated studies and reports that that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019a, Appendix, p. A–3).

[171] As discussed in section I.D, the EPA has provisionally considered studies that were highlighted by commenters and that were published after the 2019 ISA. These studies are generally consistent with the evidence assessed in the 2019 ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence.

Based on the provisional consideration in the 2020 review and the significant data gaps that existed at that time, the EPA did not include these studies within the scope of the 2022 ISA Supplement because, although these studies provide additional support for PM-related materials, the studies would not support quantitative analyses or alternative conclusions regarding these effects. As described in section I.C.5.b above, the ISA Supplement focuses on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA. In developing the ISA Supplement, the EPA focused on the non-ecological welfare effects for which the evidence supported a ''causal relationship'' and for which quantitative analyses could be supported by the evidence because those were the welfare effects that were most useful in informing conclusions in the 2020 PA. While the 2020 PA considered the broader set of evidence for materials effects, it concluded that there remained 'substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects' (U.S. EPA, 2020b).'' Therefore, the ISA Supplement did not include an evaluation of scientific evidence for PM-related materials effects. However, the EPA has once again provisionally considered new studies in this reconsideration, including the studies highlighted by the commenters, in the context of the 2019 ISA and concludes that, as in the 2020 review, these studies are not sufficient to alter the conclusions reached in the 2019 ISA regarding PM and materials effects or to provide sufficient information on which to base a secondary NAAQS. The EPA agrees there is a causal relationship between the presence of PM in the ambient air and materials effects, but to set a standard, the EPA needs not only to understand at what point materials effects become adverse to public welfare but to be able to relate specific concentrations of ambient PM to those levels of materials effects. Given the significant gaps in the evidence, particularly given that the majority of the recent evidence has been conducted outside of the U.S., establishing any quantitative relationships between particle size, concentration, chemical components, and specific measures of materials damage, such as frequency of painting or repair of materials, the EPA finds the evidence is insufficient to support a secondary NAAQS to protect against materials effects.

With regard to studies conducted outside of the U.S., including those referenced by the commenters, as described in the proposal, in reaching his proposed conclusion, the Administrator recognized that while there was some newly available information related to materials effects of PM included in the 2019 ISA, ''this evidence is primarily from studies conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2019a, section 13.4)'' (88 FR 5661, January 27, 2023). We disagree with the commenters that EPA did not provide references for these studies, nor that the lack of references inhibited the public's ability to provide comment on this proposed conclusion. First, the reference to section 13.4 in the 2019 ISA is a direct citation to the evaluation of newly available studies on PM-related materials effects, which includes citations for all materials effects evidence considered in the 2020 review and in this reconsideration. Second, section 5.3.2.1.2 of the 2022 PA considers the available scientific evidence for PM-related materials effects—including citations to the studies newly available in the 2019 ISA—and how that evidence informs conclusions regarding the adequacy of the standard (U.S. EPA, 2022b, section 5.3.2.1.2). Therefore, the EPA disagrees that the proposal failed to provide the proper references to the studies conducted outside of the U.S., and that the public was not provided the opportunity to provide comment on these studies.

Moreover, we disagree with the commenters that the EPA failed to consider quantitative information from studies available in this reconsideration. As detailed in sections 5.3.2.1.2 and 5.3.2.2 of the 2022 PA, and consistent with the information available in the 2020 review, a number of new studies are available that apply new methods to characterize PM-related effects on previously studied materials; however, the evidence remains insufficient to relate soiling or damage to specific levels of PM in ambient air or to establish quantitative relationships between PM and materials degradation. The uncertainties in the evidence identified in the 2012 review persist in the evidence in the 2020 review and in this reconsideration, with significant uncertainties and limitations to establishing quantitative relationships between particle size, concentration, chemical components, and frequency of painting or repair of materials. While some new evidence is available in the 2019 ISA, overall, the data are insufficient to conduct quantitative analyses for PM-related materials effects. Quantitative relationships have not been established between characteristics of PM and frequency of repainting or cleaning of materials, including photovoltaic panels and other energy-efficient materials, that would help inform our understanding of the public welfare implications of soiling in the U.S. (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4). Similarly, the information does not support quantitative analyses between microbial deterioration of surfaces and the contribution of carbonaceous PM to the formation of black crusts that contribute to soiling (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4). We also note that quantitative relationships are difficult to assess, in particular those characterized using damage functions as these approaches depend on human perception of the level of soiling deemed to be acceptable and evidence in this area remains limited in this reconsideration (U.S. EPA, 2022b, section 5.3.2.1.2). Additionally, we note the CASAC's concurrence with conclusions in the 2020 PA (Cox, 2019b, p. 13 of consensus responses) and the 2022 PA (Sheppard, 2022a, p. 23 of consensus responses) that uncertainties remain about the best way to evaluate materials effects of PM in ambient air. Further, no new studies are available in this reconsideration to link human perception of reduced aesthetic appeal of buildings and other objects to materials effects and PM in ambient air. Finally, uncertainties remain about deposition rates of PM in ambient air to surfaces and the interaction of PM with copollutants on these surfaces (U.S. EPA, 2022b, section 5.6).

With respect to the commenters' assertion that the EPA failed to consider information related to materials damage and degradation from oxidant concentrations and solar radiation for a variety of materials, we first note that, even assuming these sources of materials damage are within the scope of this review of the PM NAAQS, the commenter did not provide any references to the scientific studies that they suggest that the EPA did not consider. Despite the lack of a list of specific references from the commenter, we note that the 2019 ISA considered a number of studies that examined the

relationships between PM and several of the materials listed by the commenters (*e.g.,* paint, plastic, rubber). However, as described in the 2022 PA, these studies did not provide additional information regarding quantitative relationships between PM and materials that could inform quantitative analyses (U.S. EPA, 2022b, sections 5.3.2.1.2 and 5.3.2.2.2), nor did they alter conclusions regarding the adequacy of the current standard (U.S. EPA, 2022b, section 5.5).

As summarized above and in the proposal, the evidence in the 2020 review and in this reconsideration for PM-related effects on materials is not substantively changed from that in the 2012 review. There continues to be a lack of evidence related to materials effects that establishes quantitative relationships and supports quantitative analyses of PM-related materials soiling or damage. While the information available in the 2020 review and in this reconsideration continues to support a causal relationship between PM in ambient air and materials effects (U.S. EPA, 2019a, section 13.4), the EPA is unable to relate soiling or damage to specific levels of PM in ambient air and is unable to evaluate or consider a level of air quality to protect against such materials effects. Although the EPA did not propose a distinct level of air quality or a national standard based on air quality impacts (88 FR 5662, January 27, 2023), we did identify data gaps that prevented us from doing so. The EPA identified a number of key uncertainties and areas of future research (U.S. EPA, 2022b, section 5.6) that may inform consideration of the materials effects of PM in ambient air in future reviews of the PM NAAQS. The EPA notes that one commenter objected to the Administrator's proposed conclusion in the proposal (88 FR 5661, January 27, 2023) that in light of the available evidence for PM-related impacts on climate and on materials that it is appropriate not to change the existing secondary standards at this time. The EPA has explained, in both the proposal and this final action, the basis for its conclusion that there is insufficient evidence to identify any particular secondary standard or standards that would provide requisite protection against climate effects or materials damage. The EPA acknowledges that, as a result, the adoption of any distinct secondary PM standards for those effects would be inconsistent with the requirements of the CAA. The EPA is clarifying that it is not basing its decisions on secondary standards in this reconsideration to address these welfare effects because it has concluded that the available scientific evidence is insufficient to allow the Administrator to make a reasoned judgment about what specific standard(s) would be requisite to protect against known or anticipated adverse effects to public welfare from PM-related materials damage or climate effects.

Some commenters agree with the Administrator's proposed conclusion that a target level of protection for visibility of 30 dv and the level of the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ continues to be adequate to protect visibility, highlighting improvements in visibility in the U.S. Other commenters who disagree with the proposed decision indicated support for a more stringent standard for visibility impairment, although some of these commenters did not necessarily specify the alternative standard that would, in their judgment, address their concerns related to various aspects of the EPA's proposal, including the available public preference studies, specific aspects of the visibility index, and the target level of protection identified by the Administrator. Rather, most commenters focused on particular aspects of the visibility metric underlying the current secondary 24-hour $PM_{2.5}$ standard, including the form, averaging time, and target level of protection necessary to protect against visibility impairment.

With regard to the commenters' assertion that the current secondary standards are inadequate to protect the public welfare from PM-related visibility impairment, the EPA disagrees that the currently available information is sufficient to suggest that a more stringent standard is warranted. The EPA identified and addressed in great detail the limitations and uncertainties associated with the public preference studies as a part of the 2012 review (78 FR 3210, January 15, 2013). Given that the evidence related to public preferences has not substantially changed since the 2012 review, the EPA reiterated the limitations and uncertainties inherent in the evidence as a part of the 2020 PA (U.S. EPA, 2020b, section 5.5), as well as in the 2022 PA for this reconsideration (U.S. EPA, 2022b, section 5.6). The 2022 PA highlights key uncertainties associated with public perception of visibility impairment and identifies areas for future research to inform future PM NAAQS reviews, including those raised by the commenters (U.S. EPA, 2022b, section 5.6). Specifically, the EPA agrees with commenters that there are several areas where additional information would reduce uncertainty in our interpretation of the available information for purposes of characterizing visibility impairment. As described in more detail in the 2020 PA (U.S. EPA, 2020b, p. 5–41) and the 2022 PA (U.S. EPA, 2022b, p. 5–53), briefly, these areas include: (1) Expanding the number and geographic coverage of preference studies in urban, rural, and Class I areas; (2) evaluating visibility preferences of the U.S. population today, given that the preference studies were conducted more than 15 years ago, during which time air quality in the U.S. has improved; (3) accounting for the influence of varying study methods may have on an individual's response as to what level of visibility impairment is acceptable, and; (4) information on people's judgments on acceptable visibility based on factors that can influence their perception of visibility (*e.g.,* duration of impairment experiences, time of day, frequency of impairment).

However, the EPA disagrees with the commenters that the current secondary PM standards are inadequate and should be made more stringent because of the limitations and uncertainties associated with the available public preference studies. The EPA does not view the limitations of the preference studies and other available evidence as so significant as to render the EPA unable to identify a secondary standard to protect against the adverse effects of PM on visibility, but the EPA also does not believe that the limitations themselves mean that the standards are inadequate. In fact, there is a limited amount of recently available scientific evidence to further inform our understanding of public preferences and visibility impairment is recognized by the Administrator in reaching his proposed decision not to change the current secondary PM standards at this time, given that the evidence base is largely the same as at the time of the 2012 and 2020 reviews.

These same commenters further contend that the EPA failed to use the latest science to develop a visibility index, stating that the EPA failed to consider the contrast of distance methodology employed in a recent meta-analysis of available preference studies (Malm et al., 2019). Commenters claim that the EPA draws conclusions from the Malm et al. (2019) study about how to relate contrast to acceptable visibility preferences in the 2022 ISA Supplement, yet ignores the findings of the study and fails to consider the ''contrast of distance'' methodology in the 2022 PA and the proposal, thereby, in their view, departing from the CASAC's advice to consider this evidence in setting the secondary

standard. Finally, the commenters assert that the EPA did not explain why the available public preference studies are adequate for analysis using a light extinction approach but not using the contrast of distance approach, and that such differential treatment is arbitrary.

We disagree with the commenters that the EPA did not use the latest science in evaluating the visibility index, and that the EPA failed to consider the contrast of distance methodology used in Malm et al. (2019). As the commenters state, the Malm et al. (2019) study was included in the ISA Supplement (U.S. EPA, 2022a, section 4.2.1). However, the EPA disagrees with the assertion that the ISA Supplement reached conclusions about how to relate contrast to acceptable visibility preferences. The ISA Supplement provided an overview of the Malm et al. (2019) study, stating that ''[t]he main conclusion of this study was that the level of acceptable visual air quality is more consistent across studies using metrics that evaluate the distinction of an object from a background than using metrics that evaluate the greatest distance at which an object can be observed.'' Furthermore, the statements that the commenters are referencing in support of this statement (*i.e.,* U.S. EPA, 2022b, pp. 4–5–4–6) are in fact the conclusions of the study itself, rather than conclusions of the EPA. For example, the ISA Supplement notes that ''Malm et al. (2019) suggested that scene-dependent metrics like contrast, which integrate the effects of b_{ext} along the sight paths between observers and landscape features, are better predictors of preference levels than universal metrics like light extinction.'' The suggestion that the contrast of distance methodology is a better predictor than light extinction is one of the study authors, not the EPA. The EPA has not reached a conclusion on whether contrast of distance methodology would be a more appropriate indicator for a visibility index than estimated light extinction because the EPA finds that there is insufficient information in the record at this time to support that it is practical to evaluate, much less adopt, the contrast of distance methodology on a national basis. Specifically, the Malm et al. (2019) study does not provide as a part of their publication the specific input values to the equation to calculate the contrast of distance associated with the available public preference studies (*e.g.,* sight paths from the images), nor do the preference studies present or make publicly available these data in their publications. In the absence of additional studies or publicly available data to further evaluate the contrast of distance methodology, the EPA is unable to consider contrast of distance as an alternative to estimated light extinction in this reconsideration, although we note that it may be appropriate to evaluate it more closely in future reviews.

In reaching conclusions regarding the appropriate indicator for the visibility index, the 2022 PA specifically notes ''that limited new research is available on methods of characterizing visibility or on how visibility is valued by the public, such as visibility preference studies. Thus, while limited new research has further informed our understanding of the influence of atmospheric components of $PM_{2.5}$ on light extinction, the available evidence to inform consideration of the public welfare implications of PM-related visibility impairment remains relatively unchanged'' (U.S. EPA, 2022b, p. 5–50). The EPA again notes in the proposal that ''there are very few studies available that use scene-dependent metrics (*i.e.,* contrast) to evaluate public preference information, which makes it difficult to evaluate them as an alternative to the light extinction approach'' (88 FR 5649–5650, January 27, 2023). To further expand on this statement, the Malm et al. (2019) study does not provide enough information to replicate the results of their contrast of distance approach to allow for a comprehensive evaluation of the potential use of this methodology in considering the results of the public preference studies for determining the target level of protection for visibility.

Some commenters suggests that the methodology could be approximated by simply ensuring that people could always see distant scenic elements, and that characterizing typical average and/or maximal viewing distances cross different geographical areas and regions would be a straightforward Geographical Information Systems (GIS) exercise. The EPA disagrees that this assessment would be straightforward, given the lack of data establishing viewing distances in the available scientific record and the diversity of distance to scenic elements across different areas and regions of the U.S., and finds that this approach is also not practical to adopt in this reconsideration. Finally, while the Malm et al. (2019) study is using an alternative approach for evaluating public preferences and acceptability, we note that this study is evaluating the same public preference studies that have been available for the past several decades. For these reasons, the EPA disagrees with the commenters' allegation that the EPA ignored the findings of the Malm et al. (2019) study and failed to consider the contrast of distance methodology in the 2022 PA and the proposal, and ignored the CASAC's advice to consider this study. The ISA Supplement and the 2022 PA considered the Malm et al. (2019) study, along with the full body of available scientific evidence, and took into account the uncertainties and limitations associated with the evidence for visibility preferences, in reaching conclusions regarding the adequacy of the secondary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2022b, pp. 5–24–5.25, 5–50).

Several comments in support of revising the secondary 24-hour $PM_{2.5}$ standard to protect against visibility generally recommend revisions to the elements of the standard and visibility index (indicator, averaging time, form, and level) consistent with those supported by the CASAC and public comments in previous PM NAAQS reviews. Some commenters assert that the EPA's approach in the 2022 PA and in the proposal for this reconsideration did not evaluate options for alternative secondary PM standards and thereby is flawed. We address comments on the elements of a visibility index and a revised standard for visibility effects below.

As an initial matter, the EPA disagrees to the extent commenters are suggesting that the PA is legally required to analyze options for alternative standards. The PA is a document developed by the EPA in order to assist the Administrator and the CASAC in reaching conclusions regarding the adequacy of the current standards, and its scope is determined by the EPA. Moreover, the 2022 PA did assess a wide range of information relevant to the Administrator's decision and considered a range of potential standards.

First, in developing the 2022 PA and in responding to CASAC's advice and recommendations during its review of the 2021 draft PA, the EPA expanded upon its discussion of determining the target level of protection for the visibility index and considered the extent to which the available scientific information would alter regarding the visibility index and the appropriate target level of protection against PM-related visibility effects (U.S. EPA, 2022b, pp. 5–27–5–29). This detailed discussion expands the consideration of the target level of protection for the visibility index presented in the 2020 PA (U.S. EPA, 2020b) and the 2021 draft PA (U.S. EPA, 2021c), neither of which specifically considered the elements of the visibility index in determining the appropriate target level of protection. In

considering the available information in the 2022 PA, the EPA concluded that the available information continued to provide support for a visibility index with a level of 30 dv, with estimated light extinction as the indicator, a 24-hour averaging time, and a 90th percentile form, averaged over three years.

Additionally, in summarizing the air quality and quantitative information in the proposal for this reconsideration, the EPA further expands upon the discussion added to the 2022 PA related to the target level of protection in terms of a $PM_{2.5}$ visibility index. In so doing, the EPA considers even more extensively the available public preference studies and quantitative analyses (88 FR 5651–5652, January 27, 2023). In particular, there is a more detailed discussion of the public preference studies, including the levels of impairment determined to be ''acceptable'' by at least 50 percent of study participants and the methodologies used in the studies, including uncertainties and limitations associated with the methodologies (88 FR 5652, January 27, 2023). In reaching a proposed decision regarding the adequacy of the secondary PM standards, as well as the appropriate target level of protection for the visibility index, the Administrator considered the available scientific evidence and quantitative analyses, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. In so doing, the Administrator proposed to conclude that the protection provided by a visibility index based on estimated light extinction, a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv would be requisite to protect public welfare with regard to visibility impairment (88 FR 5660, January 27, 2023).

Having provisionally concluded that it was appropriate to define the target level of protection in terms of a visibility index based on estimated light extinction as described above (*i.e.,* with a 24-hour averaging time; a 3-year, 90th percentile form; and a level of 30 dv), the Administrator next considered the degree of protection from visibility afforded by the current secondary PM standards. In so doing, he considered the updated analyses of PM-related visibility impairment presented in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.2) and described in more detail in the proposal (88 FR 5656, January 27, 2023), which included estimating light extinction using multiple versions of the IMPROVE algorithm and inclusion of $PM_{10-2.5}$ data at all sites to allow for better characterization of the influence of the coarse fraction of PM on light extinction. The Administrator noted that the results of the analyses in the 2022 PA were consistent with those from the 2012 and 2020 reviews. He also recognized that, regardless of the IMPROVE equation that was used, the analyses demonstrated that the 3-year visibility metric is at or below 28 dv in all areas meting the current 24-hour $PM_{2.5}$ standard (88 FR 5657, January 27, 2023). The Administrator also noted that, in their review of the 2021 draft PA, the CASAC stated that ''[i]f a value of 20–25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour standard in the range of 25–35 $\mu g/m^3$ should be considered (Sheppard, 2022a, p. 21 of consensus responses). The Administrator recognized that while the CASAC recommended that additional justification be provided for a visibility index target level of protection of 30 dv, they did not specifically recommend that he choose an alternative level for the visibility index. Therefore, the Administrator considered the available scientific evidence, quantitative information, and the CASAC's advice in reaching his proposed conclusions. The Administrator recognized conclusions regarding the appropriate weight to place on the scientific and technical information, including how to consider the range and magnitude of uncertainties inherent in that information, is a public welfare policy judgment left to the Administrator. As such, the Administrator noted his preliminary conclusion on the appropriate visibility index (*i.e.,* with a 24-hour averaging time; a 3-year, 90th percentile form; and a level of 30 dv) and his preliminary conclusions regarding the quantitative analyses of the relationship between the visibility index and the current secondary 24-hour $PM_{2.5}$ standard. In so doing, he proposed to conclude that the current secondary standards provide requisite protection against PM-related visibility effects (88 FR 5661, January 27, 2023).

However, the Administrator additionally recognized that the available evidence on visibility impairment generally reflects a continuum and that the public preference studies did not identify a specific level of visibility impairment that would be perceived as ''acceptable'' or ''unacceptable'' across the whole U.S. population. He noted a judgment of a target level of protection, below 30 dv and down to 25 dv, could be supported if more weight was put on the public preference study performed in the Phoenix, AZ, study (BBC Research & Consulting, 2003). As described above, while the Administrator noted that the CASAC did not recommend revising the level of the current 24-hour $PM_{2.5}$ standard in their review of the 2021 draft PA, they did state that, should an alternative level be considered for the visibility index, revisions to the secondary 24-hour $PM_{2.5}$ standard should also be considered (Sheppard, 2022a, p. 21 of consensus responses). Thus, the Administrator solicited comment on the appropriateness of a target level of protection for visibility below 30 dv and down as low as 25 dv, and of revising the level of the current secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$ (88 FR 5662, January 27, 2023), and the Administrator considered these public comments in reaching his final decision on the secondary standards. Thus, the EPA disagrees that the 2022 PA and the proposal did not adequately consider options for revising the secondary PM NAAQS.

With regard to the elements of the visibility index, in considering the adequacy of the current secondary 24-hour $PM_{2.5}$ standard to protect against visibility impairment, as described in the proposal (88 FR 5658–5660, January 27, 2023), the Administrator first defined an appropriate target level of protection in terms of a PM visibility index. In considering the information available in this reconsideration and the CASAC's advice, the Administrator proposed to conclude that the protection provided by a visibility index based on estimated light extinction, a 24-hour averaging time, and 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visibility impairment (88 FR 5660, January 27, 2023).

In defining this target level of protection, the Administrator first considered the indicator of such an index. He noted that, given the lack of availability of methods and an established network for directly measuring light extinctions, a visibility index based on estimates of light extinction by $PM_{2.5}$ components derived from an adjusted version of the original IMPROVE algorithm would be most appropriate, consistent with the 2012 and 2020 reviews. As described in the proposal (88 FR 5649, January 27, 2023) and above (section V.A.2), the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The

Administrator, while recognizing that some revisions to the IMRPOVE algorithm were newly available in the 2020 review, noted that the fundamental relationship between ambient PM and light extinction has changed very little and the different versions of the IMPROVE algorithms can appropriately reflect this relationship across the U.S. (88 FR 5658–5659, January 27, 2023). As such, he judged that defining a target level of protection in terms of estimated light extinction continues to be a reasonable approach in this reconsideration.

Some commenters who criticized the EPA's interpretation and application of the Malm et al. (2019) study also contend that an indicator based on the contrast of distance would be a significant improvement over the current indicator for the visibility index and would more accurately evaluate public preferences. However, as described in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.1), while scene-dependent metrics, such as contrast, may be useful alternative predictors of preferences compared to universal metrics like light extinction, there are a very limited number of studies that use such metrics to evaluate public preferences of visibility impairment and there is a lack of scientific evidence that supports one metric over another. Moreover, the EPA finds that even if the Administrator agreed that the contrast of distance methodology was an improvement over light extinction, there is insufficient information available to evaluate and adopt contrast of distance as an indicator for a national visibility target at this time. While, in its review of the 2021 draft PA the CASAC suggested that the EPA consider this method in developing the secondary PM standards, the CASAC also noted that ''more extensive technical evaluation of the alternatives for visibility indicators and practical measurement methods'' is needed to inform future reviews of the secondary PM standards (Sheppard, 2022a, p. 22 of consensus responses). The CASAC did not recommend using a different indicator for this reconsideration, with the majority of CASAC members reiterated past advice recommending development of a visibility FRM for a directly measured $PM_{2.5}$ light extinction indicator (Sheppard, 2022a, p. 22 of consensus responses), a recommendation that was supported by other public commenters as well, and the minority of the CASAC suggested that such an FRM is not necessary. For these reasons, the EPA does not consider it feasible or appropriate to define the visibility index in terms of a contrast of distance indicator at this time.

With regard to averaging time, some commenters suggested to the EPA that a secondary standard with a different form than the primary standard may be a more relevant for welfare effects. While they do not recommend a specific alternative form, the commenters point to CASAC advice in past reviews where the CASAC stated that a subdaily standard based on daylight hours better reflects visibility impairment.

In defining the characteristics of a visibility index, the EPA continues to believe that a 24-hour averaging time is reasonable. This is in part based on analyses conducted in the 2012 review that showed relatively strong correlations between 24-hour and subdaily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction (88 FR 5659, January 27, 2023; 85 FR 82740, December 18, 2020; 78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the subdaily time periods relevant for visual perception. The EPA believes that these analyses continue to provide support for a 24-hour averaging time for the visibility index in this reconsideration. The EPA also recognizes that the longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance (88 FR 5659, January 27, 2023; 85 FR 82740, December 18, 2020; 78 FR 3226, January 15, 2013). When taken together, the available scientific information and updated analyses of calculated light extinction available in this reconsideration continue to support that a 24-hour averaging time is appropriate when defining a target level of protection against visibility impairment in terms of a visibility index.

Moreover, the EPA disagrees with commenters that a secondary $PM_{2.5}$ standard with a 24-hour averaging time does not provide requisite protection against the public welfare impacts of visibility impairment. At the time of the 2012 review, the EPA recognized that hourly or subdaily (*i.e.,* 4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related to the short-term nature of visibility impairment and the relevant viewing periods for segments of the viewing public than a 24-hour averaging time. At the time of the 2012 review, the EPA agreed that a subdaily averaging time would generally be preferable. However, the Agency noted significant data quality uncertainties associated with the instruments that would provide hourly $PM_{2.5}$ mass concentrations necessary to inform a subdaily averaging time. These uncertainties, as described in the 2012 review, included short-term variability in hourly data from available continuous monitoring methods, which would prohibit establishing a subdaily averaging time (78 FR 3209, January 15, 2013). For all of these reasons, and consistent with the 2020 review, the EPA continues to believe that a subdaily averaging time is not supported by the information available in this reconsideration.

With regard to the form of the visibility index, some commenters contend that the form used in evaluating visibility impairment is not appropriate. First, commenters contend that the EPA incorrectly stated that the CASAC did not provide advice on the 3-year, 90th percentile form of the visibility index and that the CASAC specifically recommended that the EPA further justify the metric and form, and by not doing so, the proposal arbitrarily departs from the CASAC's recommendations. The commenters also contend that the EPA fails to explain how averaging the form over three years is protective given that the public does not perceive visibility in three-year averages.

We disagree with the commenters that the EPA departed from the CASAC's recommendations that ''[t]he final PA should provide a robust justification for the daily light extinction percentile used in the analysis'' (Sheppard, 2022a, p. 22 of consensus responses). In this statement, the CASAC did not make explicit recommendations for revisions to the form of the visibility index, as the commenters assert, but rather requested additional justification for the percentile selected for the visibility index in the 2022 PA. In response to the CASAC's recommendation after reviewing the 2021 draft PA, the EPA included a new section in the 2022 PA that explicitly discusses the elements (*i.e.,* indicator, averaging time, form, and level) of the visibility index, including additional justification for the conclusions regarding the appropriate elements for the index (U.S. EPA, 2022b, pp. 5–27–5–29). In so doing, the 2022 PA recognizes that there is no new information available in this reconsideration to inform selection of an alternative form of the visibility index, and therefore, relied on the analyses presented in the 2010 UFVA that evaluated the different statistical forms of the visibility index. The 2022 PA also discusses the approach to improving visual air quality in Federal Class I areas as a part of the Regional Haze Program (U.S. EPA, 2022b, p. 5–28). Furthermore, as reflected in responding to public comments below, and in

reaching his final conclusions in section V.B.4 below, the Administrator further considers the available scientific and quantitative information, the CASAC's advice, and public comments in informing his final conclusions regarding the appropriate target level of protection for the visibility index. With regard to the commenters' assertion that the EPA did not justify why averaging the form over three years is protective, we agree with the commenters that people do not perceive visibility impairment in three year averages. As described in the 2022 PA, visibility-related effects and perceived impairment are often associated with short-term PM concentrations, and therefore, the focus of the visibility analyses is centered on the adequacy of the 24-hour $PM_{2.5}$ standard (U.S. EPA, 2022b, p. 5–29). However, as described in the 2022 PA, the 3-year average form provides stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (U.S. EPA, 2022b, p. 5–28). Occasional meteorological variability is of particular concern for the visibility index, which can be impacted by not only PM concentrations in ambient air but also relative humidity. The D.C. Circuit has previously recognized that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard. See *American Trucking Ass'ns* v. *Whitman,* 283 F.3d 355, 375–76 (D.C. Cir. 2002). The 2022 PA concluded that the available information continues to provide support for a 90th percentile form, averaged over three years, and the inclusion of additional justification for the elements of the visibility index responds to the CASAC's recommendation (U.S. EPA, 2022b, section 5.3.1.2).

Some commenters suggest that the 90th percentile form is too low and would result in 36 days being excluded annually, presuming that the public only finds it objectionable when visibility is worse than the standard on 37 or more days per year. The commenters also contend that the EPA's approach of using a 90th percentile form for the visibility index is inconsistent with the goals of the Regional Haze Program. In so doing, the commenters note that the Regional Haze Rule focuses on improving conditions on the worst days, while they argue that a 90th percentile form for the visibility index would ignore the 36 worst visibility days, rather than identifying them and reducing pollution on those days.

In reaching conclusions regarding the appropriate form of the visibility index, the EPA is following the same approach employed in past reviews of the secondary PM NAAQS, including those in the 2012 and 2020 rulemakings. In reaching conclusions regarding the appropriate form of the visibility index in the 2011 PA, the EPA considered the percentile forms of the visibility index assessed in the 2010 PA (*i.e.,* 90th, 95th, 98th) along with the approach for improving visual air quality under the Regional Haze Program. In so doing, the 2011 PA notes that the Regional Haze Program targets the 20% most impaired days for improvements in visual air quality in Federal Class I areas (*i.e.,* the days more impaired than the 80th percentile). The 2011 PA recognized that to increase the likelihood of improving visual air quality on the worst days, the form of the visibility index should be set well above the 80th percentile. The 2011 PA further concluded that a 90th percentile form would represent the median of the distribution of the 20% most impaired days, and meeting a visibility index with a 90th percentile form would mean that 90% of the days have visual air quality that is at or below the level of the visibility index and would reasonably expected to lead to improvements in visual air quality for the 20% most impaired days (U.S. EPA, 2011, p. 4–59). The 2022 PA noted that there is no new information from public preference studies that would inform the Administrator's consideration of the appropriate form for the visibility target index, and reached conclusions consistent with those of 2011 PA. However, as discussed below, the EPA disagrees that a focus on the 90th percentile ''ignores'' any days with worse visibility. It is possible to examine past patterns of air quality to judge the relationship between the 90th percentile and higher percentiles, and to assess whether achieving a 90th percentile visibility target will also result in air quality improvements, where necessary, at higher percentiles. Based on its assessment of past air quality and potential alternative percentiles for the form, the EPA judged that a 90th percentile would appropriately achieve improved air quality both above and below that percentile.

Some commenters suggest that the analyses conducted in the 2010 UFVA are based on a different metric than the 24-hour average being considered in the reconsideration, that the analyses are outdated and irrelevant. Therefore, the commenters assert that relying on the analyses in the 2010 UFVA is not a rational justification for the use of a 90th percentile for the visibility index in this reconsideration. Moreover, these commenters state that, in past reviews, both the EPA and the CASAC have considered and recommended a 98th percentile form, but the proposal does not consider the 98th percentile.

These commenters assert that the 2010 UFVA was not considering the same metric under consideration here. However, the EPA was citing to the 2010 UFVA for the conclusion that there are correlations between different statistical forms of the visibility index. To confirm whether these correlations occur under recent air quality, we conducted additional air quality analyses evaluating the visibility index using the current percentile form (*i.e.,* 90th) and two alternative forms (*i.e.,* 95th and 98th).[172] While a higher percentile form would further limit the number of days with peak PM-related light extinction, the analyses confirm that a 90th percentile form is effective in limiting visibility impairment at higher percentiles. Based on these analyses, depending on which version of the IMPROVE equation is used to estimate light extinction, the differences in the 3-year averages of estimated light extinction for the 90th, 95th, and 98th percentile forms are small. For example, in areas that meet the current 24-hour $PM_{2.5}$ standard, for light extinction estimated using the original IMPROVE equation, all sites have light extinction estimates for a 90th percentile form at or below 26 dv, for a 95th or 98th percentile form at or below 29 dv.[173] In most locations, when estimating light extinction based on the original IMPROVE equation, the difference between a 95th or 98th percentile form and a 90th percentile form is generally less than 3 dv.[174] As noted in previous reviews, a change of 1 to 2 dv in light extinction under many viewing conditions will be perceived as a small, but noticeable, change in the appearance of a scene, regardless of the initial amount of visibility impairment (88 FR 5657, January 27, 2023; U.S. EPA, 2004b; U.S. EPA, 2010b). Thus, differences between a 90th percentile form and a 95th or 98th percentile form remain small, and for any of these forms of the visibility index, the estimated light extinction based on the original IMPROVE equation in areas meeting the current secondary 24-hour $PM_{2.5}$ standard is below the upper end of the range of the levels considered for the visibility index (*i.e.,* below 30 dv).

Some commenters disagree with the EPA's proposed conclusion that a level of 30 dv is appropriate for the visibility index and support a lower level in order to provide increased protection against visibility impairment. Commenters who support a revised level for the visibility index state that a target level of protection of 30 dv would mean that less than 10% of participants in the public preference studies, other than the Washington, DC, study, would accept visibility conditions above 29 dv. These commenters further suggest that a 75% acceptability, rather than 50% acceptability, is requisite to protect visibility sources, which would be on average a level of 21 dv when using the light extinction method or 18 dv when using the contrast of distance method. These commenters argue that, based on the available information, a target level of protection for the visibility index of approximately 20 dv would be more appropriate, and therefore, the level of the secondary 24-hour $PM_{2.5}$ standard should be strengthened to 25 $\mu g/m^3$. Other commenters who support a revised level for the visibility index suggest that public preference studies with longer sight paths to distant landscape features or with lower target levels than those in the Washington, DC study, such as the Phoenix study, would support a lower level. These commenters support revising the target level of protection for the visibility index to a 25 dv, and revising the level of the secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$, suggesting that in low relative humidity environments, 25 dv is consistent with $PM_{2.5}$ concentrations of less than 25 $\mu g/m^3$.

Some commenters state that EPA's justification for setting a target level of protection at the upper end of the 20 to 30 dv range is arbitrary. These commenters state that the EPA's reliance on the standard operating in many regions and circumstances as support for the upper end of the range is irrational and illegal. Moreover, these commenters contend that EPA provided no rational connection between the Regional Haze Program and the proposed decision to set the target level of protection at the upper end of the range. They suggest that the EPA proposed to rely exclusively on the Regional Haze Program to protect visibility in Class I areas and to give visibility in these areas no weight in considering the secondary PM standard and that it is not rational to entirely ignore visibility in Class I areas when setting the secondary standard. These commenters assert that the Regional Haze Program provides no rational basis for a target level of protection at the upper end of the range, nor does the EPA identify one.

Some commenters contend that the EPA failed to justify the adequacy of the current secondary annual $PM_{2.5}$ standard, noting that the secondary 24-hour and annual $PM_{2.5}$ standards work together to provide protection against short- and long-term effects of $PM_{2.5}$. These commenters point to CASAC comments on the 2021 draft PA and the comments of an individual CASAC member's support for strengthening the secondary annual $PM_{2.5}$ standard to provide increased protection against climate and materials effects over time. They contend that EPA arbitrarily failed to discuss the secondary annual $PM_{2.5}$ standard not only in the proposal, but also in the 2022 PA and in the 2020 final decision.

The EPA recognizes that the selection of the target level of protection for the visibility index is fundamentally a public welfare policy judgment for the Administrator. The Administrator is tasked by the CAA to judge when visibility impairment becomes an adverse effect on public welfare. It is clear that visibility impairment can become adverse to public welfare, but the Administrator does not consider that every deciview of impairment is adverse to public welfare. In considering the point at which visibility impairment becomes adverse to public welfare, such that the attainment of the secondary PM NAAQS would prevent the adverse effect, the Administrator gives weight to the public preference studies as to when visibility impairment is unacceptable. At the same time, the Administrator recognizes the limitations of these studies, which have been detailed in the proposal and the 2022 PA. Similarly, the EPA discussed the Regional Haze program in the proposal to highlight that there is a distinct program to protect against visibility impairment in Class I areas, and the existence of that program is relevant to the Administrator's judgment about the level of visibility impairment that is adverse to public welfare under CAA 109(d), because in determining what is requisite the Administrator is primarily considering visibility impairment outside of Class I areas.

[172] Gantt, B., and Hagan, N. (2023). Analysis of Percentile Forms of the Visibility Index. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

[173] Gantt, B., and Hagan, N. (2023). Analysis of Percentile Forms of the Visibility Index. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

[174] Gantt, B., and Hagan, N. (2023). Analysis of Percentile Forms of the Visibility Index. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

In considering how to use the results of the public preference studies, the Administrator concludes that a 50th acceptability criterion is an appropriate tool. The Administrator's task is to set standards that are neither more stringent nor less stringent than necessary, and a 50% acceptability criterion seems most appropriate to use in judging when visibility impairments become adverse, because it should more closely represent when the median person would find the impairment to be adverse. The Administrator notes this conclusion is consistent with the approach adopted in the Denver study by Ely et al. (1991) where the 50% acceptability criterion for urban visibility was first presented. This study discussed the use of the 50% acceptability criteria as a reasonable basis for setting a standard to protect visibility in urban areas. In doing so, Ely et al. (1991) noted that the 50% acceptability criterion divided the slides into two groups—those judged acceptable and those judged unacceptable by a majority of people in the study—and therefore, was reasonable since it defines the point where the majority of the study participants began to judge levels of visibility impairment as unacceptable (Ely et al., 1991).

In considering the appropriate target level of protection, we next look to the available public preference studies, noting that the selecting of the range of 20 to 30 dv for the target level of protection for the visibility index is informed by the 50% acceptability values from these studies. The Denver, CO, (Ely et al., 1991) and British Columbia, Canada, (Pryor, 1996) studies met the 50% acceptability criteria at 20 dv and 19–23 dv, respectively (U.S. EPA, 2022b, Table D–8). As described in the proposal, these studies used photographs that were taken at different times of the day and on different days to capture a range of light extinction levels needed for the preference studies (88 FR 5652, January 27, 2023). Compared to studies that used computer-generated images (*i.e.,* those in Phoenix, AZ, and Washington, DC) there was more variability in scene appearance in these older studies that could affect preference rating and includes uncertainties associated with using ambient measurements to represent sight path-averaged light extinction values rather than superimposing a computer-generated amount of haze onto the images. When using photographs, the intrinsic appearance of the scene can change due to meteorological conditions (*i.e.,* shadow patterns and cloud conditions) and spatial variations in ambient air quality that can result in ambient light extinction measurement not being representative of the sight-path-averaged light extinction. Computer-generated images, such as those generated with WinHaze, do not introduce such uncertainties, as the same base photograph is used (*i.e.,* there is no intrinsic change in scene appearance) and the modeled haze that is superimposed on the photograph is determined based on uniform light extinction throughout the scene. Because of the uncertainties and limitations associated with the Denver, CO, and British Columbia, Canada, the EPA concludes that it is appropriate to place less weight on these studies, and to instead focus on the public preference studies that were designed to reduce these uncertainties and limitations.

In so doing, we focus on the public preference studies that use computer-generated images (*i.e.,* those in the Phoenix, AZ, and Washington, DC) studies. As described in the proposal, the use of computer-generated images have less variability in scene appears than in those studies that use photographs taken on different days and at different times of the days (*i.e.,* those in the Denver, CO, study) that would be likely to influence preference rating and introduces uncertainties associated with using ambient measurements to present sight path-averaged light extinction values rather than superimposing a computer-generated amount of haze onto the images (88 FR 5652, January 27, 2023).

The Phoenix, AZ, public preference study (BBC Research & Consulting, 2003) had several strengths compared to some of the other public preference studies. The Phoenix, AZ, study had the largest number of participants (385 in 27 separate focus group sessions) of all of the public preference studies, with a sample group designed to be demographically representative of the Phoenix population at that time. The age range in the Phoenix study was also more inclusive (18–65+), with the distribution of the study participants corresponding reasonably well to the overall age distribution in the 2000 U.S. Census for the Phoenix area (BBC Research & Consulting, 2003). Furthermore, the 21 images used in the Phoenix, AZ, study were developed using the WinHaze software with visual air quality ranging from 15 to 35 dv, and the view was toward the southwest, including downtown Phoenix, with the Sierra Estrella Mountains in the background at a distance of 25 miles. This study had the least noisy preference results, perhaps because a larger, more representative group of participants combined with the use of computer-generated images resulted in the smoother distribution of responses of ''acceptable'' visual air quality. Based on the EPA's evaluation of the public preference studies in the 2012 review, the 50% ''acceptable'' criteria was met at approximately 24 dv (U.S. EPA, 2010, Table 2–3).

We also consider the public preferences for the Washington, DC, studies (Abt Associates, 2001; Smith and Howell, 2009). The 2001 Washington, DC study included nine participants, and the 2009 Washington, DC, study replicated the 2001 study with 26 additional participants. Similar to the Phoenix study, the Washington, DC, studies also had the strength of having the 20 images included in the study generated using WinHaze with visual air quality ranging from 9 to 45 dv. The study depicted a scene of a panoramic view of the Potomac River, the National Mall, and downtown Washington, DC. All of the distinct buildings in the scene were within four miles and the higher elevations in the background were less than 10 miles from where the image was taken from the Arlington National Cemetary in Virginia. The 50% ''acceptable'' criteria was met at approximately 29 dv (U.S. EPA, 2010, Table 2–3).

As described in more detail in the proposal, visibility preferences can vary by location, and such differences may arise based on the differences in the cityscape scene that is depicted in the images (88 FR 5652, January 27, 2023). In considering the geographical differences between the public preference studies, we recognize that the methodological differences between the studies may influence the resulting ''acceptable'' level of visibility impairment. In the Phoenix, AZ, study, the image depicted mountains in the background and urban features in the foreground, whereas the Washington, DC, study depicted nearby buildings in the image without mountains in the distance. As an initial matter, we note that the object of interest to the study participant could differ across the studies based on the scenes included in the images being evaluated—with the mountains being of greater interest in the images in the Phoenix, AZ, study, despite also depicting buildings that are similar to those shown and presumed to be of interest in the images in the Washington, DC, study (88 FR 5652, January 27, 2023). We also agree with the commenters that the distance between the object of interest and the camera is an important consideration in

evaluating the public preference studies. Objects at greater distances from the camera location (such as those in the Phoenix, AZ, study which had a maximum distance of 42 km (U.S. EPA, 2022b, Table D–8)) have a greater sensitivity to light extinction, which alone could explain differences in preferences but coupled with an object of greater interest results in lower acceptable levels of visibility impairment. Conversely, objects at closer distances from the camera location (such as those in the Washington, DC, study which had a maximum distance of 8 km (U.S. EPA, 2022b, Table D–8)) have less sensitivity to light extinction, which coupled with objects of interest (compared to the mountainous views in the Phoenix, AZ, study) result in higher acceptable levels of visibility impairment. These studies clearly demonstrate that there are differences in the public preferences across the studies depending on the images that are used, in particular the object of interest to the study participant depicted in the image and the distance of the sight path to the object, and that such differences can influence preference results.

However, we note that these uncertainties and limitations have persisted from past reviews, and there is very little new information to inform conclusions regarding the interpretation of these results with regard to the target level of protection. In selecting a target level of protection, and in considering the CASAC's advice in their review of the 2021 draft PA and public comments, we conclude that it is appropriate to consider the information from the public preference studies in Washington, DC, and Phoenix, AZ, and in so doing, that it is appropriate to place weight on both of these studies in reaching conclusions on the appropriate target level of protection. The EPA recognizes that the scenes depicted in these two studies are different and may influence public preferences of visibility impairment, but notes these studies can be considered together as providing information about different areas across the U.S. with variations in the scenes that people are likely to most commonly encounter. The scene depicted in the images used in the Washington, DC, study have a mix of buildings, landmarks, and open space. On the other hand, the scene depicted in the Phoenix, AZ, study included a mix of buildings in the foreground and with more distant mountains in the background. The Administrator considers it appropriate to consider these studies together because in combination, they provide a greater diversity of scenes, which is more likely to be representative of scenes people typically experience around the country (*e.g.,* not only in eastern metropolitan statistical areas, but also in western areas with different vistas). In considering these two studies together, the EPA recognizes that, first, the ''object of interest'' is a subjective judgment left to the participants of the public preference studies, and second, the images in these two studies may differ in terms of sensitivity to changes in light extinction because of the distance between the object of interest in the scene and the camera. As noted by the public commenters, the sight path for the images in the public preference studies is an important consideration in reaching conclusions regarding the appropriate target level of protection for the visibility index. In addition, the Administrator judges that giving weight to multiple studies is a more appropriate approach than focusing on a single study, particularly where the study design (including the representativeness of the participants and the scenes depicted in the images) may be important for interpreting the results of the public preference studies for informing conclusions regarding the visibility index. Given these considerations and taking into consideration public comments on the target level of protection for the visibility index, the Administrator recognizes that it is more appropriate to consider a broader range of public preferences, reflecting a broader range of scenes, by putting significant weight on both the Washington, DC, and Phoenix, AZ, studies. In so doing, he reaches the conclusion that it would be appropriate to identify secondary PM standards that generally limit visibility impairment to a level between the two studies.

The Administrator next considers what target level of protection would be appropriate based on the available information from these public preference studies. He first recognizes that, in the 2012 and 2020 final decisions, the then-Administrators selected a target level of protection of 30 dv, based on the upper end of the range. In so doing, the then-Administrators judged that it was appropriate to place more weight on the uncertainties associated with the public preference studies in reaching their conclusions. However, in this reconsideration, the current Administrator, while continuing to recognize that substantial uncertainties remain and that there is relatively limited new information regarding public preferences of visibility impairment, judges that it is important to balance the weight placed on uncertainties with the strength of the scientific evidence. As such, the Administrator concludes that it is appropriate to consider a target level of protection within the range of 20 to 30 dv. He further concludes that in selecting a target level within that range it is appropriate to place weight on both the mid-point of the range, as supported by the study in Phoenix, AZ, as well as the upper end, as supported by the Washington, DC, study. The Administrator notes that these two studies both employ similar methodologies that are subject to fewer uncertainties than older public preference studies (including their use of WinHaze to reduce uncertainties in the preference solicitations) although he notes that the Phoenix, AZ, study yielded the best results of the four public preference studies in terms of the least noisy preference results and the most representative selection of participants. Furthermore, he notes the differences between the scenes used for each study and finds that consideration of these studies together is more appropriate in selecting a national target for visibility protection than considering either study alone. Thus, in considering this information, along with the uncertainties and limitations of the public preference studies, the Administrator judges that it would be appropriate to select a target level of protection based on placing equal weight on the upper end of the range (*i.e.,* 30 dv) and the middle of the range (*i.e.,* 24 dv based on the Phoenix, AZ, study) in order to identify a nationwide target for protection against visibility impairment. In so doing, the Administrator concludes that a visibility index with a target level of protection of 27, defined in terms of estimated light extinction, with a 24-hour averaging time and a 3-year, 90th percentile form, would provide adequate protection against PM-related visibility effects on public welfare. Such a target level of protection balances the information from two key studies reflecting different participant preferences for different vistas in different parts of the country, appropriately weighting both near-field and more distant landscape features that may be of importance to public perceptions of visibility.

The Administrator notes that the available evidence indicates that the relationship between PM and light extinction is complex, depending on factors such as PM composition, size fraction, and age of the particles in ambient air, as well as relative

humidity. These factors can vary across the country based on differences in regional influences, as well as meteorological conditions that can vary spatially and temporally in different areas. The Administrator also recognizes that this variability, coupled with the age of the PM depending on the distance from the source to the monitor location, also complicates the selection of which IMPROVE equation is most appropriate in different areas, although he notes that different IMPROVE equations will yield similar, but not identical, results. In so doing, the Administrator takes note of the figures presented in the 2022 PA, which depict the comparisons using the original IMPROVE equation (Figure 5–3), the revised IMPROVE equation (Figure 5–4), and the Lowenthal & Kumar equation (Figure 5–6), as well as the estimated light extinction values for the three different equations presented in Table D–7.

The Administrator notes that when light extinction is calculated using the original IMPROVE equation, all 60 sites have 3-year visibility metrics below 28 dv, 58 sites are at or below 25 dv, 26 sites are at or below 20 dv, and of the two sites above 25 dv one is at 26 dv and the other has a 24-hour $PM_{2.5}$ design value of 56 μg/m³ (*i.e.,* well above the current 24-hour standard). Results are similar for other IMPROVE equations.[175] Based on these analyses, and consistent with the results of similar analyses in the 2012 review and the 2020 PA, the Administrator concludes that the current secondary 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m³, maintains the visibility index below 27 dv, and in fact, the current standard maintains air quality such that many areas have visibility index values that range between 15 and 25 dv for all three IMPROVE equations. In the areas that meet the secondary 24-hour $PM_{2.5}$ standard, all locations were below 27 dv when using the original and revised IMPROVE equation and all but three locations were at or below 27 dv when using the Lowenthal & Kumar IMPROVE equation. Three locations (two in California and one in Utah) had air quality that was at 28 dv when the Lowenthal & Kumar IMPROVE equation was used. As described in more detail in section V.A.1.3, we recognize that there are differences in the inputs for the three IMPROVE equations that can influence the resulting estimated light extinction values. The higher multiplier for converting OC to OM in the Lowenthal & Kumar IMPROVE equation (*i.e.,* a multiplier of 2.1) may be more appropriate in more remote locations where there is more aged and oxygenated organic PM than in urban locations. The three locations with air quality at 28 dv are all in urban areas (downtown Los Angeles, CA; Rubidoux, CA; Salt Lake City, UT) and tend to have higher levels of nitrate and OC, especially during the wintertime when peak $PM_{2.5}$ concentrations typically occur. In these locations, it may be more appropriate to use either the original or revised IMPROVE equation, which have multipliers of 1.4 and 1.8, respectively, in order to refine the inputs such that estimated light extinction in these locations is more accurately characterized based on site-specific characteristics.

We also note that the four areas that exceed the secondary 24-hour $PM_{2.5}$ standard also generally had air quality that was below 27 dv in terms of the visibility index, with only two locations experiencing a visibility index above 27 dv. One location that exceeds the secondary 24-hour $PM_{2.5}$ standard had a visibility index of 29 dv using the original IMPROVE equation, while two locations were 30 and 32 dv using the Lowenthal & Kumar IMPROVE equation. We believe attainment and maintenance of the secondary 24-hour $PM_{2.5}$ standard will result in improved air quality in these areas, such that the visibility index values for these areas will decrease even further.

The Administrator recognizes that in concluding that it is appropriate to identify secondary PM standards that generally limit visibility impairment to as low as 27 dv in terms of the visibility index, the current secondary PM standards continue to provide protection against visibility impairment associated with a visibility index as low as, or even lower than, 27 dv. In so doing, he notes that when meeting the current 24-hour $PM_{2.5}$ standard, all sites have a visibility index at or below 27 dv with the original and revised IMPROVE equations, and all but three sites at or below 27 dv with the Lowenthal and Kumar IMPROVE equation. Furthermore, the Administrator notes that this conclusion is consistent with the CASAC's advice who, in their review the 2021 draft PA, stated that ''[i]f a value of 20–25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25–35 μg/m³ should be considered'' (Sheppard, 2022a, p. 21 of consensus responses).

Thus, the Administrator concludes that weight on both the upper end of the range of target levels of protection for the visibility index identified in previous reviews and the mid-point of the range, as presented by the Phoenix, AZ, public preference study, and focusing on a target level of protection of 27 dv, he still judges the current secondary 24-hour $PM_{2.5}$ standard requisite to achieve that target because the standard generally maintains the visibility index at or below 27 dv such that more stringent standards are not warranted.

The EPA agrees with the commenters that the secondary PM standards work together to provide protection against short- and long-term effects of both fine and coarse particles (U.S. EPA, 2022b, section 5.5; 88 FR 5661, January 27, 2023). However, the EPA disagrees with commenters that we failed to discuss the secondary annual $PM_{2.5}$ standard in the proposal, 2022 PA, and the 2020 final notice and that we failed to justify the adequacy of the secondary annual $PM_{2.5}$ standard. As described in the 2022 PA and the proposal, we recognize that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (U.S. EPA, 2022b, section 5.3.1.2; 88 FR 5654, January 27, 2023). Analyses in the 2019 ISA found that mass scattering from $PM_{10-2.5}$ was relatively small (less than 10%) in the eastern and northwestern U.S., whereas mass scattering was much larger in the Southwest (more than 20%), particularly in southern Arizona and New Mexico (U.S. EPA, 2019, section 13.2.4.1, p. 13–36). Given the relationship between visibility and $PM_{2.5}$ along with the short-term nature of visibility effects, we focus more on the adequacy of the secondary 24-hour $PM_{2.5}$ standard for providing protection against visibility impairment (U.S. EPA, 2022b, section 5.3.1.2; 88 FR 5653, January 27, 2023). In reaching his proposed conclusions, the Administrator clearly states that he ''recognizes that the current suite of secondary standards (*i.e.,* the 24-hour $PM_{2.5}$, 24-hour PM_{10}, and annual $PM_{2.5}$ standards) together provide . . . control for both fine and coarse particulates and long- and short-term visibility and non-visibility (*e.g.,* climate and materials) effects related to PM in ambient air'' (88 FR 5661, January 27, 2023). Thus, by explaining how the secondary standards work together to provide protection from adverse effects, why we focus on the secondary 24-hour $PM_{2.5}$ standard as

[175] When light extinction is calculated using the revised IMPROVE equation, all 60 sites have 3-year visibility metrics below 28 dv, 56 sites are at or below 25 dv, and 26 sites are at or below 20 dv. When light extinction is calculated using the Lowenthal and Kumar IMPROVE equation, 59 sites have 3-year visibility metrics below 28 dv, 45 sites are at or below 25 dv, and 15 sites are at or below 20 dv. The one site with a 3-year visibility metric of 32 dv exceeds the secondary 24-hour $PM_{2.5}$ standard, with a design value of 56 μg/m³ (see U.S. EPA, 2022b, Appendix D, Table D–3).

most relevant to visibility impairment, and how the Administrator selected the target level of protection for the visibility index, we have addressed the CASAC's request to support the proposed decision to revise the secondary 24-hour $PM_{2.5}$ standard while retaining the secondary annual $PM_{2.5}$ standard. The commenters also cite to an individual CASAC member's comments for the review of the 2021 draft PA who stated ''[f]or the limited scope of this reconsideration review, I see no reason to not simply set the Secondary equal to the Primary PM Standards, whatever they may be'' (Sheppard, 2022a, p. A–3). This CASAC member did not provide a supporting rationale for revising the secondary standards to levels equal to the primary standards. Although areas across the country are required to attain both the primary and secondary $PM_{2.5}$ standards so air quality is unaffected by the Administrator's decision not to revise the secondary standards to be equal to the primary standards, as described in responding to comments above, the CAA provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect public welfare from known or anticipated adverse effects associated with the presence of the pollutant in ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. The final decision on the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. In reaching his proposed and final decisions regarding the adequacy of the current secondary PM standards, the Administrator considered the available scientific information and analyses about welfare effects, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. In so doing, the Administrator concluded that the currently available scientific evidence and quantitative analyses, including uncertainties and limitations, do not call into question the adequacy of the current secondary PM standards and that the current secondary PM standards should be retained, without revision. The Administrator's judgments and decisions on the primary and secondary standards are independent and consider different aspects of the available scientific evidence and information in reaching conclusions regarding the adequacy of the standards in protecting against PM-related health and welfare effects.

4. Administrator's Conclusions

This section summarizes the Administrator's considerations and conclusions related to the current secondary $PM_{2.5}$ and PM_{10} standards and presents the rationale for his decision that no change is required for those standards at this time. The CAA provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. The final decision on the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. The decision should draw on the scientific information and analyses about welfare effects, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which scientists agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act.

Given these requirements, the Administrator's final decision in this reconsideration is a public welfare policy judgment that draws upon the scientific and technical information examining PM-related visibility impairment, climate effects and materials effects, including how to consider the range and magnitude of uncertainties inherent in that information. The Administrator recognizes that his final decision is based on an interpretation of the scientific evidence and technical analyses that neither overstates nor understates their strengths and limitations, or the appropriate inferences to be drawn. In particular, the Administrator notes that the assessment of when visibility impairment is adverse to public welfare requires a public welfare policy judgment informed by available scientific and quantitative information.

In considering the adequacy of the current secondary PM standards in this reconsideration, the Administrator has carefully considered the: (1) Policy-relevant evidence and conclusions contained in the 2019 ISA and 2022 ISA Supplement; (2) the quantitative information presented and assessed in the 2022 PA; (3) the evaluation of this evidence, the quantitative information, and the rationale and conclusions presented in the 2022 PA; (4) the advice and recommendations from the CASAC; and (5) public comments. In the discussion below, the Administrator gives weight to the 2022 PA conclusions, with which the CASAC generally concurred during their review of the 2019 draft PA and 2021 draft PA, as summarized in section IV.B.1 of the 2020 final notice and section V.D.1 of the 2022 proposal, and takes note of key aspects of the rationale for those conclusions that contribute to his decision in this reconsideration. After giving careful consideration to all of this information, the Administrator judges that no change is required for the secondary PM standards at this time.

In considering the 2022 PA evaluations and conclusions, the Administrator takes note of the overall conclusions that the non-ecological welfare effects evidence and quantitative information are generally consistent with what was considered in the 2020 final decision and in the 2012 review (U.S. EPA, 2022b, section 5.5). The scientific evidence for non-ecological welfare effects in this reconsideration is largely the same as that available in the 2019 ISA and 2020 PA. As described in section I.C.5.b above, the 2022 ISA Supplement included a limited number of newly available studies on PM-related visibility effects. This newly available evidence on visibility effects, along with the full body of non-ecological welfare effects evidence assessed in the 2019 ISA, reaffirms conclusions on the visibility, climate, and materials effects recognized in the 2020 final decision and in the 2012 review, including key conclusions on which the standards are based. Further, as discussed in more

detail above, the updated quantitative analyses of visibility impairment for areas meeting the current standards in the 2022 PA support the adequacy of the current secondary PM standards to protect against PM-related visibility impairment. The Administrator also recognizes that uncertainties and limitations continue to be associated with the available scientific evidence and quantitative information.

With regard to the current evidence on visibility effects, as summarized in the 2022 PA and discussed in detail in the 2019 ISA and ISA Supplement, the Administrator notes the long-standing body of evidence for PM-related visibility impairment. As in previous reviews, this evidence continues to demonstrate a causal relationship between PM in ambient air and effects on visibility (U.S. EPA, 2019a, section 13.2). The Administrator recognizes that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. Therefore, as in previous reviews, he considers the degree to which the current secondary standards protect against PM-related visibility impairment and the degree to which PM-related visibility impairment is adverse to public welfare. In particular, in recognizing the short-term nature of visibility impairment along with the fact that $PM_{2.5}$ is the size fraction that contributes most to light extinction, the Administrator especially focuses on the adequacy of the current secondary 24-hour $PM_{2.5}$ standard in providing protection against PM-related visibility effects judged to be adverse. The Administrator also considers the protection provided by the current secondary 24-hour $PM_{2.5}$ standard against PM-related visibility impairment in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, suburban, rural, and Federal Class I areas across the U.S. Programs implemented to meet the secondary PM standards, along with the requirements of the Regional Haze Program established for protecting against visibility impairment in Class I areas, would be expected to improve visual air quality across all areas of the country.

As described in the proposal (88 FR 5658, January 27, 2023), the Administrator recognizes that the Regional Haze Program was established by Congress specifically to achieve ''the prevention of any future, and the remedying of existing, impairment of visibility in mandatory Class I areas, which impairment results from man-made air pollution,'' and that Congress established a long-term program to achieve that goal (CAA section 169A). In adopting section 169, Congress set a goal of eliminating anthropogenic visibility impairment at Class I areas, as well as a framework for achieving that goal which extends well beyond the planning process and timeframe for attaining the secondary PM NAAQS. Recognizing that the Regional Haze Program will continue to contribute to reductions in visibility impairment in Class I areas, consistent with his proposed conclusions, the Administrator concludes that addressing visibility impairment in Class I areas is largely beyond the scope of the secondary PM standards and that setting the secondary 24-hour $PM_{2.5}$ standard at a level that would remedy visibility impairment in Class I areas would result in standards that are more stringent than is requisite.

In further considering what standards are requisite to protect against adverse public welfare effects from visibility impairment, the Administrator concludes that it is appropriate to use an approach consistent with the approach used past reviews (88 FR 5650, January 27, 2023). He first identifies an appropriate target level of protection in terms of a PM visibility index that takes into account the factors that influence the relationship between PM in ambient air and visibility (*i.e.,* size fraction, species composition, and relative humidity). He then considers the air quality analyses conducted in the 2022 PA that examine the relationship between the PM visibility index and the current secondary 24-hour $PM_{2.5}$ standard in locations that meet the current 24-hour $PM_{2.5}$ and PM_{10} standards (U.S. EPA, 2022b, section 5.3.1.2).

In reaching conclusions regarding the target level of protection, the Administrator first considers the characteristics of the visibility index and defines its elements (indicator, averaging time, form, and level). With regard to the indicator for the visibility index, the Administrator continues to recognize that, consistent with the conclusions of the 2022 PA and the CASAC's advice in their review of the 2021 draft PA, there is a lack of availability of methods and an established network for directly measuring light extinction. Therefore, the Administrator concludes that it continues to be appropriate to using an index based on estimates of light extinction by $PM_{2.5}$ components based on the IMPROVE algorithm. In so doing, the Administrator recognizes that the fundamental understanding of the relationship between ambient PM and light extinction has generally changed very little over time; however, several versions of the IMPROVE equation have been developed and evaluated that could be used to estimate light extinction. As at the time of the proposal, the Administrator recognizes that the results of the quantitative analyses in the 2022 PA that examined three versions of the IMPROVE equation indicate that there are very small differences in estimates of light extinction between the equations, and that it is not always clear that one version of the IMPROVE equation is more appropriate for estimating light extinction across the U.S. than other versions of the IMPROVE algorithm (88 FR 5659, January 27, 2023). He also recognizes that the selection of inputs to the IMPROVE equation (*e.g.,* the multiplier for OC to OM) may be more appropriate on a regional basis rather than a national basis when calculating light extinction, and notes the CASAC's advice that PM-visibility relationships are region specific (Sheppard, 2022a, p. 21 of consensus responses). The Administrator further notes that neither the CASAC nor public commenters recommended a specific IMPROVE equation or an approach for using different IMPROVE equations across the U.S. Therefore, given the absence of a robust monitoring network to directly measure light extinction, the Administrator concludes that light estimated light extinction, as calculated using one or more versions of the IMPROVE algorithms, continues to be the most appropriate indicator for the visibility index.

Having reached the conclusion that estimated light extinction is the appropriate indicator for the visibility index, the Administrator next considers the appropriate averaging time and form of the index. With regard to the averaging time and form, the Administrator notes that in previous reviews, a 24-hour averaging time was selected and the form was defined as the 3-year average of annual 90th percentile values. As at the time of proposal, the Administrator recognizes that the available information continues to provide support for the short-term nature of visibility effects. He further recognizes that no new information is available in this reconsideration to inform his conclusions regarding averaging time, and therefore, he considers past analyses of 24-hour and subdaily $PM_{2.5}$ light extinction to inform his conclusions on averaging time. As described in the proposal (88 FR 5659, January 27, 2023) and in responding to comments in section V.B.3 above, prior

analyses demonstrated that there are strong correlations between 24-hour and subdaily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction, indicating that a 24-hour averaging time is an appropriate surrogate for the subdaily time periods associated with when individuals experience visibility impairment and that a longer averaging time may also be less influenced by atypical conditions and/or atypical instrument performance. The Administrator also notes that the CASAC did not provide advice or recommendations with regard to the averaging time of the visibility index, although some public commenters referenced CASAC advice in past reviews that a subdaily standard based on daylight hours would better reflect the public welfare effects of public perceptions of visibility impairment than a 24-hour standard. However, in considering the available scientific and quantitative information, as well as the CASAC's advice in their reviews of the 2019 draft PA and 2021 draft PA, the Administrator concludes that the 24-hour averaging time continues to be appropriate for the visibility index because it is an appropriate surrogate for subdaily time periods and results in a more stable target.

With regard to the form of the visibility index, the Administrator notes the approach in other NAAQS that a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. He recognizes that using a 3-year average provides stability from the occasional effects of inter-annual meteorological variability (including relative humidity) that can result in unusually high pollution levels for a particular year (88 FR 5659, January 27, 2023) and recognizes that a stable standard contributes to the benefits of the NAAQS by ensuring that attainment strategies are designed to address non-transient problems and achieve durable air quality improvements. For these reasons, he concludes that a 3-year average continues to be appropriate.

In considering the percentile that would be appropriate with the 3-year average, the Administrator recognizes that there is very little new information available in this reconsideration to inform selection of an alternative form of the visibility index and that the appropriate form requires the exercise of public welfare policy judgment. In selecting the appropriate target level of protection for the visibility index, the Administrator is required to assess when visibility impairment becomes adverse to public welfare, weighing both the degree of visibility impairment (in dv) and the frequency of such impairment (through the form). As with the mass-based PM air quality standard, the target level of protection for the visibility index must be selected in conjunction with the form to determine the appropriate stringency. In so doing, consistent with approaches in past reviews, the Administrator first notes that the Regional Haze Program targets the 20% most impaired days for improvements in visual air quality in Class I areas, which are the days above the 80th percentile form of the visibility index. The Administrator concludes that a percentile form set at the 80th percentile would not be likely to sufficiently improve visual air quality on the worst days based on the visibility index. In considering the information available in past reviews regarding the form of the visibility index, as well as the analysis of alternative forms based on recent air quality discussed above, the Administrator notes that a 90th percentile form would represent the median of the distribution of the 20% most impaired days, and meeting a visibility index with a 90th percentile form would reasonably be expected to lead to improvements in visual air quality for days both above and below the 90th percentile (88 FR 5660, January 27, 2023). In reaching his conclusion that a 90th percentile would appropriately achieve improved air quality both above and below that percentile, the Administrator took into consideration assessments of air quality data and potential alternative percentiles for the form. The Administrator further notes that, consistent with the conclusions in the 2011 PA and 2020 PA, the 2022 PA concluded that there is no new information from public preference studies that would suggest that a 90th percentile form is not appropriate. The Administrator also considers air quality analyses described above in responding to public comments regarding the percentile form of the visibility index. In particular, the Administrator notes that while a higher percentile form (*i.e.,* 95th or 98th) would somewhat further limit the number of days with peak PM-related light extinction, the differences in the 3-year averages of estimated light extinction for the 90th, 95th, and 98th percentile forms are small. For example, he notes that for the original IMPROVE equation, in areas that meet the current 24-hour $PM_{2.5}$ standard, all sites have light extinction estimates for a 90th percentile form at or below 26 dv, and for a 95th or 98th percentile form light extinction estimates are at or below 29 dv.[176] He further notes that, in most locations when estimating light extinction based on the original IMPROVE equation, the difference between a 95th or 98th percentile form and a 90th percentile form is generally less than 3 dv.[177] Moreover, the Administrator concludes that a 90th percentile form achieves a very high degree of control but appropriately targets the group of worst days, rather than the few very worst days. Based on the available information and these analyses, the Administrator concludes that the information does not indicate that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction to a greater degree, nor did the CASAC provide advice or recommendations related to the form of the visibility index. Therefore, the Administrator judges that it remains appropriate to define a visibility index in terms of a 24-hour averaging time and form based on the 3-year average of annual 90th percentile values.

With regard to the level of the visibility index, as at the time of proposal, the Administrator continues to recognize that there is very little new information available to inform his judgment regarding the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the visibility preference studies,[178] and therefore, the range of 20 to 30 dv identified in the 2022 PA remains appropriate for considering the level of the visibility index. The Administrator also recognizes that the uncertainties and limitations associated with the public preferences identified in the 2012 and 2020 reviews continue to persist, and that these limitations and uncertainties contributed to the decisions in 2012 and 2020 that a level at the upper end of the range (*i.e.,* 30 dv) was selected. The Administrator specifically notes that, while the studies

[176] Gantt, B., and Hagan, N. (2023). Analysis of Percentile Forms of the Visibility Index. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

[177] Gantt, B., and Hagan, N. (2023). Analysis of Percentile Forms of the Visibility Index. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

[178] For reasons stated above and described in the 2022 PA and proposal, the Administrator does not find it appropriate to use the most recent preference study based on the Grand Canyon study area (Malm et al., 2019) for purposes of identifying a target level of protection for the visibility index.

are methodologically similar, there are a number of factors that can influence comparability across the studies and that the available studies may not capture the full range of visibility preferences in the U.S. population, as described in more detail in section V.D.3 of the 2022 proposal (88 FR 5659–5660, January 27, 2023). The Administrator also notes the CASAC's advice in their review of the 2021 draft PA that there are a limited number of visibility preference studies available to inform the Administrator's judgment regarding the appropriate target level of protection for the visibility index (Sheppard, 2022a, p. 21 of consensus responses). In considering the available information, including uncertainties and limitation, and the CASAC's advice, the Administrator proposed to conclude that it is appropriate to consider a target level of protection for the visibility index within the range of 20 to 30 dv, and that establishing a target level of protection at the upper end of the range was appropriate. In so doing, the Administrator proposed to conclude that the protection provided by a visibility index based on estimated light extinction, a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set to a level of 30 dv would be requisite to protect public welfare with regard to visibility impairment.

However, at the time of proposal, the Administrator recognized that the available evidence on visibility impairment generally reflects a continuum and that the public preference studies do not provide information about the specific level for which visibility impairment would be ''acceptable'' or ''unacceptable'' across the country, and that alternative target levels of protection could be supported. At that time, in soliciting public comments, the Administrator recognized that other interpretations, assessments, and judgments based on the available welfare effects evidence for this reconsideration could be possible (88 FR 5662, January 27, 2023).

With regard to the appropriate target level of protection for the visibility index, the Administrator first notes that while the public preference studies were conducted in several geographical areas across the U.S., and they provide insight into regional preferences for visibility impairment, none of the studies identify a specific level of visibility impairment that would be perceived as ''acceptable'' or ''unacceptable'' across the whole U.S. population. He also noted that there have been significant questions about how to set a standard for visibility that is neither overprotective nor underprotective for some areas of the U.S. As described in the proposal (88 FR 5660, January 27, 2023), in establishing the Regional Haze Program to improve visibility in Class I areas, Congress noted that ''as a matter of equity, the national ambient air quality standards cannot be revised to adequately protect visibility in all areas of the country.'' H.R. Rep. 95–294 at 205. For the reasons noted above, in reaching his proposed decision regarding visibility impairment, the Administrator recognized that he is not seeking to set a standard that would eliminate visibility impairment in Class I areas, but significant uncertainties remain regarding how to judge when visibility impairment becomes adverse to public welfare across the range of daily outdoor activities for Americans across the country.

In reaching final conclusions regarding the available information, along with the CASAC's advice and public comments, the Administrator again considers what constitutes an appropriate target level of protection, and in particular considers whether a target level of protection below 30 dv is warranted. In so doing, he first notes the variability in public preferences of visibility impairment as demonstrated by the available public preferences, which support a range of potential target levels of protection for the visibility index from 20 to 30 dv. He also notes that this range informed the 2012 and 2020 then-Administrators final decisions that a target level of protection at the upper end of the range (*i.e.,* 30 dv) would be most appropriate, given the uncertainties and limitations associated with the public preference studies. As described in in section V.B.3 above in responding to public comments, the Administrator recognizes that a number of factors can influence public preferences across studies, in particular due to the types of scenes depicted in the images as well as the distances at which the objects of interest are located from the camera. Furthermore, the Administrator recognizes the small number of public preference studies currently available makes precise interpretations of their results challenging for determining a nationally appropriate target level of visibility protection. The Administrator also recognizes that the CASAC, in their review of 2021 draft PA, reiterated that PM-visibility relationships are region-specific based on aerosol composition, and that several public commenters emphasized the importance of the sight path distance in the images when considering how to interpret the public preference studies.

In this reconsideration, the Administrator judges that in determining when visibility impairment becomes adverse to public welfare for purposes of the secondary NAAQS, while continuing to recognize that substantial uncertainties remain and that there is relatively limited new information regarding public preferences of visibility impairment, it is important to balance the weight placed on uncertainties with the strength of the scientific evidence. In so doing, the Administrator first concludes that, consistent with previous reviews and his proposed decision, it remains appropriate to consider a target level of protection within the range of 20 to 30 dv. However, in further considering the available scientific and quantitative information, CASAC advice, and public comments, he further concludes that in selecting a target level within that range it is appropriate to place weight on both the middle of the range, as supported by the study in Phoenix, AZ, as well as the upper end, as supported by the Washington, DC, study. In so doing, he notes that the Washington, DC, and Phoenix, AZ, studies employ similar methodologies that are subject to fewer uncertainties than older public preference studies (including their use of WinHaze to reduce uncertainties in the preference solicitations) although he does note that the Phoenix, AZ, study yielded the best results of the four public preference studies in terms of the least noisy preference results and the most representative selection of participants. Further, the Administrator judges that this approach would take into account scenes that are similar to both the Washington, DC, study and Phoenix, AZ, study, which would be more representative of the ''typical'' scenes encountered across more areas of the U.S. than an approach that places weight on just one study or on studies conducted in certain geographical areas of the country. In considering this information, along with the uncertainties and limitations of the public preference studies, the Administrator judges that it would be appropriate to select a target level of protection based on placing equal weight on the upper end of the range (*i.e.,* 30 dv) and the middle of the range (*i.e.,* 24 dv based on the Phoenix, AZ, study) in order to provide protection against visibility impairment in different geographical areas of the U.S. For these reasons, the Administrator concludes that a visibility index with a target level of protection of 27 dv,

defined in terms of estimated light extinction, with a 24-hour averaging time and a 3-year, 90th percentile form, would provide adequate protection against PM-related visibility effects. In reaching this conclusion, the Administrator judges that such a target level of protection balances the information from these two key public preference studies in such a way appropriately weighs both near-field and more distant landscape features that may be of importance to public perceptions of visibility.

In further considering the appropriate target level of protection for the visibility index, the Administrator again recognizes the complexity of the relationship between PM and light extinction which is dependent on a number of factors, including PM composition, size fraction, and age of the particles in ambient air, as well as relative humidity. As noted in responding to comments above, these factors can vary geographically across the U.S. and local or regional meteorological conditions can also vary spatially and temporally. These factors are critical inputs to the IMPROVE equation and can influence the resulting estimated light extinction such that it is not a straightforward comparison between estimated light extinction in one area of the country versus another. Moreover, the Administrator recognizes that there is variability in estimated light extinction depending on the version of the IMPROVE equation that is used. As described in more detail in the 2022 PA and the proposal, and in reaching his decisions on the indicator of the visibility index above, the Administrator notes that the 2022 PA concluded that one version of the IMPROVE equation is not more accurate or precise in estimating light extinction, and that difference in locations may support the selection of inputs into the IMPROVE equation or of the appropriate IMPROVE equation to estimate light extinction on a regional basis rather than on a national basis.

In considering the available information, including variations in both public preferences of visibility impairment and estimates of light extinction using one or more IMPROVE equation, as well as the CASAC's advice in their review of the 2019 draft PA and 2021 draft PA and public comments, the Administrator judges that a target level of protection of 27 dv would be appropriate. In so doing, he concludes that a target level of protection above 27 dv would not provide adequate protection against PM-related visibility impairment based on the 50% acceptability values when both the Washington, DC, and Phoenix, AZ, studies are considered. However, he also notes that when considering the 50% acceptability values from studies conducted in different areas of the U.S. and with different scenes and images depicted, the available public preference studies do not provide a ''bright line'' at and above which visibility impairment is considered adverse to public welfare. He further recognizes that, as discussed just above, there are a number of region-specific factors that can influence light extinction, and thereby influence visibility impairment, as well as variations in public preferences of visibility impairment based on the available studies, that complicate selection of a single target level of protection that would be appropriate for a national visibility index. While the Administrator recognizes that the uncertainties and limitations associated with public preferences of visibility and estimating light extinction have persisted over the last several PM NAAQS reviews, he also recognizes that in reaching conclusions regarding the appropriate target level of protection for the visibility index also involves public welfare policy judgments regarding how to appropriately consider the particular uncertainties around identifying when visibility impairment becomes adverse to public welfare, and the limitations on relying on the public preference studies.

The Administrator also places weight on the high degree of spatial and temporal variability in PM composition and relative humidity across the U.S. in considering a target level of protection. This approach of establishing a target level of protection that takes into account 50% acceptability values from both eastern and western sites is a more appropriate basis for determining the requisite level of protection against known or anticipated adverse effects on public welfare across diverse locations, *i.e.,* a standard that is neither more nor less stringent than necessary nationwide. Specifically, the Administrator judges that a target level of protection for the visibility index focused on maintaining estimated light extinction between the upper end of the range of the target levels of protection (*i.e.,* 30 dv based on the Washington, DC, study) and the middle of the range (*i.e.,* 24 dv based on the Phoenix, AZ, study) to be more appropriate for a nationwide standard to protect against visibility impairment compared to a value derived from one location or one type of scene alone. For these reasons, in selecting a target level of protection, the Administrator concludes that a target level of protection somewhere between the upper end and middle of the range is appropriate because he judges that this approach, in conjunction with the Regional Haze program, is sufficient, but not more stringent than necessary, to protect against adverse effects on public welfare. Thus, he concludes a secondary 24-hour $PM_{2.5}$ NAAQS should be evaluated based on its ability to provide protection against visibility impairment associated with estimated light extinction of 27 dv based on estimated light extinction, a 24-hour averaging time, and a 90th percentile form, averaged over 3 years.

Having concluded that it is appropriate to identify a target level of protection in terms of a visibility index based on estimated light extinction as described above, the Administrator next considers the degree of protection from visibility impairment afforded by the current secondary PM standards. He considers the updated analyses of PM-related visibility impairment presented in the 2022 PA (U.S. EPA, 2022b, section 5.3.1.2) and described in section V.B.1.a of the proposal, and notes that the results of the analyses are consistent with the results from the 2012 and 2020 reviews.

Taking into consideration the full body of scientific evidence and technical information concerning the known and anticipated effects of PM on visibility impairment, the Administrator concludes that the current secondary $PM_{2.5}$ and PM_{10} standards are requisite to protect against PM-related visibility impairment. While the inclusion of the coarse fraction had a relatively modest impact on calculated light extinction in the analyses presented in the 2022 PA, he recognizes the continued importance of the PM_{10} standard given the potential for larger impacts in locations with higher coarse particle concentrations, such as in the southwestern U.S., for which only a few sites met the criteria for inclusion in the analyses in the 2022 PA (U.S. EPA, 2019a, section 13.2.4.1; U.S. EPA, 2022b, section 5.3.1.2).

With regard to the adequacy of the secondary 24-hour $PM_{2.5}$ standard, the Administrator notes that, in their review of the 2021 draft PA, the CASAC stated that ''[i]f a value of 20–25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25–35 $\mu g/m^3$ should be considered'' (Sheppard, 2022a, p. 21 of consensus responses). The Administrator recognizes that the CASAC recommended that the Administrator provide additional justification for a visibility index target

of 30 dv but did not specifically recommend that he choose an alternative level for the visibility index. The Administrator carefully considered the advice of CASAC and the public comments and concluded that a lower target level of visibility was appropriate in order to properly reflect both a broader set of studies and a broader range of vistas that were the subject of those studies. However, in their review of the 2021 draft PA, the CASAC recognized that even a visibility index target in the range of 20–25 dv could still warrant retention of the current secondary 24-hour $PM_{2.5}$ standard. The Administrator also considers the advice from the CASAC in their review of the 2019 draft PA, who ''recogniz[ed] that uncertainties. . .remain about the best way to evaluate'' PM-related visibility effects (Cox, 2019b, p. 13 consensus responses). The Administrator considered the CASAC's advice, together with the available scientific evidence and quantitative information, in reaching his conclusions.

The Administrator recognizes that conclusions regarding the appropriate weight to place on the scientific and technical information examining PM-related visibility impairment, including how to consider the range and magnitude of uncertainties inherent in that information, is a public welfare policy judgment left to the Administrator. In reaching his final decision in 2020, the then-Administrator noted that the available evidence regarding visibility effects had changed very little since the 2012 review, specifically recognizing that, as evaluated in the 2019 ISA, there were no new visibility studies that were conducted in the U.S. and there was little new information available with regard to acceptable levels of visibility impairment in the U.S. (85 FR 82742, December 18, 2020). As such, the then-Administrator concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, a 90th percentiles form averaged over three years, set at a level of 30 dv, was requisite to protect public welfare against visibility impairment (85 FR 82743, December 18, 2020). He also recognized that there was some new information to inform quantitative analyses of light extinction, but that the results of the analyses conducted in the 2020 PA were consistent with those from the 2012 review. The then-Administrator recognized that the analyses demonstrated that the 3-year visibility metric was at or below about 30 dv in all areas that met the current secondary 24-hour $PM_{2.5}$ standard, and was below 25 dv in most of those areas (85 FR 82743, December 18, 2020). Therefore, the Administrator judged that the secondary 24-hour $PM_{2.5}$ standard provided sufficient protection for visual air quality of 30 dv, which he judged appropriate (88 FR 82744, December 18, 2020). In this reconsideration, the ISA Supplement evaluated newly available studies on public preferences for visibility impairment and/or development methodologies or conducted quantitative analyses of light extinction. In considering the available scientific and quantitative information, including that newly available in this reconsideration, the current Administrator reached the same preliminary conclusions in the notice of proposed rulemaking regarding the 3-year visibility index and the current secondary PM standards as the then-Administrator in the 2020 final decision. However, in light of public comments on the proposal, the Administrator has further considered the available scientific evidence and information, as well as the CASAC's advice regarding visibility effects in their review of the 2021 draft PA. In so doing, the Administrator judges that it is appropriate to place more weight on certain aspects of the evidence that he had placed less weight on in reaching his proposed conclusions (*i.e.,* he focused on the both the middle and the upper end of the range of the 50% acceptability values from the available public preference studies). As such, the Administrator notes his conclusion on the appropriate visibility index (*i.e.,* with a 24-hour averaging time; a 3-year, 90th percentile form; and a level of 27 dv), which takes into account the regional variations in public preferences and equations for estimating light extinction, and his conclusions regarding the quantitative analyses of the relationship between the visibility index and the current secondary 24-hour $PM_{2.5}$ standard. In so doing, the Administrator concludes that the current secondary standards provide requisite protection against PM-related visibility effects.

With respect to climate effects, as at the time of proposal, the Administrator recognizes that a number of improvements and refinements have been made to climate models since the time of the 2012 review. However, despite continuing research and the strong evidence supporting a causal relationship with climate effects (U.S. EPA, 2019a, section 13.3.9), the Administrator notes that there are still significant limitations in quantifying the contributions of the direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). He also recognizes that models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km), compared to simulations at the global scale (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Moreover, the effects of PM on climate are diverse as well as uncertain. Depending on the circumstances, the radiative forcing effects of PM in the atmosphere can vary, such that positive forcing could result in warming of the Earth's surface, whereas a negative forcing could result in cooling (U.S. EPA, 2019a, section 13.3.2.2). The resulting uncertainty leads the Administrator to conclude that the scientific information available in this reconsideration remains insufficient to quantify, with confidence, the impacts of ambient PM on climate in the U.S. (U.S. EPA, 2022b, section 5.3.2.2.1) and that there is not an adequate scientific basis to link attainment of any particular PM concentration in ambient air in the U.S. to specific climate effects. Consequently, the Administrator judges that there is insufficient information at this time to revise the current secondary PM standards or to promulgate a distinct secondary standard to address PM-related climate effects.

With respect to materials effects, the Administrator notes that the available evidence continues to support the conclusion that there is a causal relationship with PM deposition (U.S. EPA, 2019a, section 13.4). He recognizes that deposition of particles in the fine or coarse fractions can result in physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the effects of natural weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. While some recent evidence on materials effects of PM is available in the 2019 ISA, the Administrator notes that this evidence is primarily from studies conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2019a, section 13.4). Given the limited amount of information on the quantitative relationships between PM and materials effects in the U.S., and uncertainties in the degree to which those effects could be adverse to the public welfare, the Administrator judges that the available scientific information

remains insufficient to quantify, with confidence, the public welfare impacts of ambient PM on materials and that there is insufficient information at this time to revise the current secondary PM standards or to promulgate a distinct secondary standard to address PM-related materials effects.

Taken together, the Administrator concludes that the scientific and quantitative information for PM-related non-ecological welfare effects (*i.e.,* visibility, climate, and materials),[179] along with the uncertainties and limitations, supports the current level of protection provided by the secondary PM standards as being requisite to protect against known and anticipated adverse effects on public welfare. For visibility impairment, this conclusion reflects his consideration of the evidence for PM-related light extinction, together with his consideration of updated air quality analyses of the relationship between the visibility index and the current secondary 24-hour $PM_{2.5}$ standard and the protection provided by the current secondary $PM_{2.5}$ and PM_{10} standards. For climate and materials effects, this conclusion reflects his judgment that, although it remains important to maintain secondary $PM_{2.5}$ and PM_{10} standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, it is appropriate not to change the existing secondary standards at this time and that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate and materials effects at this time. As such, the Administrator recognizes that current suite of secondary standards (*i.e.,* the 24-hour $PM_{2.5}$, 24-hour PM_{10}, and annual $PM_{2.5}$ standards) together provide such control for both fine and coarse particles and long- and short-term visibility and non-visibility (*e.g.,* climate and materials) effects related to PM in ambient air. His conclusions on the secondary standards are consistent with advice from the CASAC, which noted substantial uncertainties remain in the scientific evidence for climate and materials effects, as well as the majority of public comments on the secondary PM standards. Thus, based on his consideration of the evidence and analyses for PM-related welfare effects, as described above, and his consideration of CASAC advice and public comments on the secondary standards, the Administrator concludes that it is appropriate not to change those standards (*i.e.,* the current 24-hour and annual $PM_{2.5}$ standards, 24-hour PM_{10} standard) at this time.

[179] As noted earlier, other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM.

C. Decision on the Secondary PM Standards

For the reasons discussed above and taking into account information and assessments presented in the 2019 ISA, ISA Supplement, and 2022 PA, advice from the CASAC, and consideration of public comments, the Administrator concludes that the current secondary PM standards are requisite to protect public welfare from known or anticipated adverse effects and is not changing the standards at this time.

VI. Interpretation of the NAAQS for PM

The EPA is finalizing revisions on data calculations in appendix K for PM_{10} and appendix N for $PM_{2.5}$. Revisions to appendix K make the PM_{10} data handling procedures for the 24-hour PM_{10} standards more consistent with those of other NAAQS pollutants and codify existing practices. Revisions to appendix N update references to the revision(s) of the standards and change data handling provisions related to combining data from nearby monitoring sites to codify existing practices that are currently being implemented as the EPA standard operating procedures.

A. Amendments to Appendix K: Interpretation of the NAAQS for Particulate Matter

The EPA proposed to modify its data handling procedures for the 24-hour PM_{10} standard in appendix K to part 50 (88 FR 5662, January 27, 2023). The proposed modifications include: (1) Revising design value calculations to be on a site-level basis, (2) codifying site combinations to maintain a continuous data record, and (3) clarifying daily validity requirements for continuous monitors. The purpose of these modifications is to make the data handling procedures for the 24-hour PM_{10} standard more consistent with those of other NAAQS pollutants and codify existing practices that are currently being implemented as EPA standard operating procedures.

The EPA received few comments on these proposed appendix K revisions, the majority of which were supportive.

One commenter was not supportive of the proposed appendix K revision to site-level PM_{10} design values, asserting that it would amount to an imposition of a more stringent PM_{10} standard due to the potential high bias of FEMs. The EPA disagrees with this assertion because site-level design values would combine data from any high biased FEM with other monitors at the site rather than calculate a monitor-level design value with data solely from that high-biased FEM. The EPA tested the impact of calculating site-level PM_{10} design values for the 2019–2021 period by assigning the lowest parameter occurrence code as the primary monitor and calculating site-level design values. Most resulting site-level design values were either identical to or in-between the multiple monitor-level design values at the site. Combining data from two or more monitors also has the benefit of increasing the number of valid sample days at many sites. For the 2019–2021 test period, approximately 10% of the sites with more than one monitor went from having multiple invalid design values to a single valid design value.

One commenter was not supportive of a footnote in the preamble of the NPRM stating that in the absence of a designated primary monitor at a given site, the default primary monitor would be one with the most complete data record (88 FR 5662, January 27, 2023). Because the procedure for calculating PM_{10} design values on a site-level basis being finalized here will require monitoring agencies to designate a primary monitor for each site in their annual network plans (88 FR 5694, January 27, 2023; App. K, 1.0(b)), the EPA agrees with the commenter that this footnote was unnecessary.

Therefore, the EPA is finalizing these appendix K revisions as proposed.

B. Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$

The EPA proposed to modify its data handling procedures for the annual and 24-hour $PM_{2.5}$ standards in appendix N to part 50 (88 FR 5663, January 27, 2023). These proposed revisions include: (1) Updating references to the revisions of the standards rather than stating the specific level, and (2) codifying site combinations to maintain a continuous data record. The purpose of both modifications is to codify existing practices that are currently being implemented as the EPA standard operating procedures.

The EPA received few comments on these revisions in the proposed rule, with most supportive of the appendix N revisions.

Although the EPA did not propose or request comment on this issue, one commenter suggested that appendix N be revised to only allow data from the primary monitor to be used in $PM_{2.5}$ NAAQS designations asserting that it would add flexibility. The EPA disagrees with the commenter's assertion that this would add flexibility because it could force agencies to run

their FRMs on a daily schedule or potentially lead to invalid design values if manual sampling interruptions or laboratory issues impact FRM data completeness. This change would also be undesirable because it could reduce by two-thirds the number of days used in calculations for the annual and 24-hour $PM_{2.5}$ design values at many sites.

Therefore, the EPA is finalizing these appendix N revisions as proposed.

VII. Amendments to Ambient Monitoring and Quality Assurance Requirements

The EPA is finalizing revisions to ambient air monitoring requirements for PM to improve the usefulness of and appropriateness of data used in regulatory decision making. These changes focus on ambient monitoring requirements found in 40 CFR parts 50 (appendix L), 53, and 58 with associated appendices (A, B, C, D, and E). These changes include addressing updates in the approval of reference and equivalent methods, updates in quality assurance statistical calculations to account for lower concentration measurements, updates to support improvements in PM methods, a revision to the $PM_{2.5}$ network design to account for at-risk populations, and updates to the Probe and Monitoring Path Siting Criteria for NAAQS pollutants. The EPA also took comment on how to incorporate data from next generation technologies into Agency efforts. A summary of the comments received is included in this section.

A. Amendment to 40 CFR Part 50 (Appendix L): Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere—Addition of the Tisch Cyclone as an Approved Second Stage Separator

The EPA proposed a change to the FRM for $PM_{2.5}$ (40 CFR part 50, appendix L), the addition of an alternative $PM_{2.5}$ particle size separator to that of the Well Impactor Ninety-Six (WINS) and the Very Shape Cut Cyclone (VSCC) size separators (88 FR 5663, January 27, 2023). The new separator is the TE–$PM_{2.5}$C cyclone manufactured by Tisch Environmental Inc.,[180] Cleves Ohio, which has been shown to have performance equivalent to that of the originally specified WINS impactor with regards to aerodynamic cutpoint and $PM_{2.5}$ concentration measurement. In addition, the new TE–$PM_{2.5}$C has a significantly longer service interval than the WINS and is comparable to that of the VSCC separator. Generally, the TE–$PM_{2.5}$C is also physically interchangeable with the WINS and VSCC where both are manufactured for the same sampler. The proposed change would allow either the WINS, VSCC, or TE–$PM_{2.5}$C to be used in a $PM_{2.5}$ FRM sampler. As is the case for the WINS and VSCC, the TE–2.5C is now also an approved size separator for candidate $PM_{2.5}$ FEMs. Currently, the EPA has designated one $PM_{2.5}$ sampler configured with TE–$PM_{2.5}$C separator as a Class II $PM_{2.5}$ equivalent method and one as a $PM_{10\text{-}2.5}$ equivalent method. Upon promulgation of this change to appendix L, these instruments would be redesignated as $PM_{2.5}$ and $PM_{10\text{-}2.5}$ FRMs, respectively. Owners of such samplers should contact the sampler manufacturer to receive a new reference method label for the samplers.

The EPA received only one comment regarding this proposed change, which was supportive. Therefore, the EPA is finalizing this change to Appendix L as proposed.

B. Issues Related to 40 CFR Part 53 (Reference and Equivalent Methods)

The EPA proposed to clarify the regulations associated with FRM and FEM applications for review by the EPA (88 FR 5664, January 27, 2023). Revisions were also proposed in instances where current regulatory specifications are no longer pertinent and require updating. In addition, the EPA proposed to correct a compiled a list of noted minor errors in the regulations associated with the testing requirements and acceptance criteria for FRMs and FEMs in part 53. These errors are typically not associated with the content of **Federal Register** documents but often relate to transcription errors and typographical errors in the electronic CFR (eCFR) and printed versions of the CFR.

1. Update to Program Title and Delivery Address for FRM and FEM Applications

The EPA proposed a change to 40 CFR 53.4(a) to update the delivery address for FRM and FEM Applications and Modification Requests, as well as update the name of the program responsible for their review (88 FR 5664, January 27, 2023). These revisions are due solely to organizational changes and do not affect the structure or role of the Reference and Equivalent Methods Designation Program in reviewing new FRM and FEM application requests and requests to modify existing designated instruments. The EPA received no comments on this revision and, therefore, the EPA is finalizing this revision as proposed.

2. Requests for Delivery of a Candidate FRM or FEM Instrument

The EPA proposed a change to 40 CFR 53.4(d), which currently allows the EPA to request only candidate $PM_{2.5}$ FRMs and Class II or Class III equivalent methods for testing purposes as part of the applicant review process (88 FR 5664, January 27, 2023). The EPA proposed to revise this section to enable requesting any candidate FRM, FEM, or a designated FRM or FEM associated with a Modification Request, regardless of NAAQS pollutant type or metric. The EPA received no comments on these revisions; therefore, the EPA is finalizing this revision as proposed.

3. Amendments to Requirements for Submission of Materials in 40 CFR 53.4(b)(7) for Language and Format

The EPA proposed a change to 40 CFR 53.4(b)(7) to specify that all written FRM and FEM application materials must be submitted to the EPA in English in MS Word format and that submitted data must be submitted in MS Excel format (88 FR 5664, January 27, 2023). The EPA received no comments on these revisions; therefore, the EPA is finalizing this section as proposed.

4. Amendment to Designation of Reference and Equivalent Methods

The EPA proposed a change to 40 CFR 53.8(a) to clarify the terms of new FRM and FEM methods to ensure that candidate samplers and analyzers are not publicly announced, marketed, or sold until the EPA's approval has been formally announced in the **Federal Register** (88 FR 5664, January 27, 2023). The EPA received no comments on these revisions; therefore, the EPA is finalizing this section as proposed.

5. Amendment to One Test Field Campaign Requirement for Class III $PM_{2.5}$ FEMs

The EPA proposed a change to 40 CFR 53.35(b)(1)(ii)(D) that involves field comparability tests for candidate Class III $PM_{2.5}$ FEMs, including the requirement that a total of five field campaigns must be conducted at four separate sites, A, B, C, and D (88 FR 5664, January 27, 2023). The existing Site D specifications require that the site ''shall be in a large city east of the Mississippi River, having characteristically high sulfate concentrations and high humidity levels.'' However, dramatic decreases in ambient sulfate concentration make it difficult for applicants to routinely meet the high sulfate concentration requirement. Therefore, the EPA proposed to revise the Site D specifications to read ''shall be in a large

[180] Mention of commercial names does not constitute EPA endorsement.

city east of the Mississippi River, having characteristically high humidity levels.'' Only one comment was received on this proposed revision, which was supportive. Therefore, the EPA is finalizing the revision to 40 CFR 53.35(b)(1)(ii)(D), as proposed.

6. Amendment to Use of Monodisperse Aerosol Generator

The EPA proposed a change to 40 CFR 53.61(g), 53.62(e), and Table F–1 that involves the wind tunnel evaluation of candidate PM_{10} inlets and candidate $PM_{2.5}$ fractionators under static conditions, which requires the generation and use of monodisperse calibration aerosols of specified aerodynamic sizes (88 FR 5664, January 27, 2023). In the current regulations, the TSI Incorporated Vibrating Orifice Aerosol Generator (VOAG) is the only monodisperse generator that is approved for this purpose. However, TSI Incorporated no longer manufacturers nor supports the VOAG. Therefore, a commercially available monodisperse aerosol generator (Model 1520 Fluidized Monodisperse Aerosol Generator, MSP Corporation, Shoreview, MN) has been added to list of approved generators for this purpose. No comments were received on this revision; therefore, the EPA is finalizing this revision as proposed.

7. Corrections to 40 CFR Part 53 (Reference and Equivalent Methods)

Certain provisions of 40 CFR 53.14, Modification of a reference or equivalent method, incorrectly state an EPA response deadline of 30 days for receipt of modification materials in response to an EPA notice. Per a 2015 amendment (80 FR 65460, 65416, Oct. 26, 2015), all EPA response deadlines for modifications of reference or equivalent methods are 90 days from day of receipt. Thus, the EPA proposed a correction to specify the correct 90-day deadline (88 FR 5664, January 27, 2023).

Requirements for Reference and Equivalent Methods for Air Monitoring of Criteria Pollutants identifies the applicable 40 CFR part 50 appendices and 40 CFR part 53 subparts for each criteria pollutant. The four rows in the section for $PM_{10-2.5}$ erroneously do not include the footnote instruction that the aforementioned pollutant alternative Class III requirements may be substituted in regard to Appendix O to Part 50—Reference Method for the Determination of Coarse Particulate Matter as $PM_{10-2.5}$ in the Atmosphere.

Table B–1 specifies that the interference equivalent for each interferent is ±0.005 ppm for both the standard-range and lower-range limits, with the exception of nitric oxide (NO) for the lower-range limit per note 4. When testing the lower range of SO_2, the limit for NO is ±0.003 ppm, therefore, an incorrect lower limit (±0.0003) is currently stated in note 4 for this exception to the SO_2 lower range limit. Thus, the EPA proposed a correction to Table B–1 to specify the correct limit in note 4 (88 FR 5664, January 27, 2023).

After the EPA received an inquiry regarding the interaction of NO and O_3, the EPA investigated the interferent testing requirements stated by 40 CFR part 53, subpart B. The EPA has determined that during the 2011 SO_2 amendment and subsequent 2015 O_3 amendment, several typographical errors were introduced into Table B–3, the most significant of which is the omission of note 3, which instructs the applicant to not mix the pollutant with the interferent. Thus, the EPA proposed revisions to Table B–3 to correct these errors (88 FR 5664, January 27, 2023).

Additionally, appendix A to subpart B of part 53 provides figures depicting optional forms for reporting test results. Figure B–3 lists an incorrect formula: the lower detectible limit section is missing the proper operator in the LDL calculation formula and Figure B–5 lists an incorrect calculation metric, and there is a typesetting error in the calculation of the standard deviation. The EPA proposed to correct the typesetting errors and noted other errors to be corrected in several formulas provided throughout § 53.43 (88 FR 5664, January 27, 2023).

The EPA proposed a revision to 40 CFR 53.43(a)(2)(xvi), 53.43(b)(2)(iv), and 53.43(b)(2)(iv) to correct typographical errors in equations.

The EPA proposed a revision to Table C–4 of part 53 Subpart C (88 FR 5700). This change is related to field comparability tests of candidate $PM_{2.5}$, $PM_{10-2.5}$, and PM_{10} FEMs, which requires testing at wide range of ambient concentrations. For this reason, Table C–4 specifies a minimum number of valid sample sets to be conducted at specified high concentrations. However, due to the dramatic decrease in ambient PM concentrations in the past two decades, these number of valid test days at high concentrations has been difficult to achieve. Accordingly, the EPA proposed to revise the testing specifications for high concentration events in Table C–4 to reflect current levels of ambient PM for all three PM metrics. In addition to the revision of the ambient PM concentration specifications to Table C–4, there are also several entry errors that required correction.

The EPA received no comments on these proposed revisions; therefore, the EPA is finalizing the changes as proposed.

C. Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)

1. Quality Assurance Requirements for Monitors Used in Evaluations for National Ambient Air Quality Standards

In the proposal, the EPA described how we evaluated the quality system as part of the PM NAAQS reconsideration (88 FR 5665, January 27, 2023). In this section, the EPA identified several areas for improvement in steadily declining average ambient $PM_{2.5}$ concentrations across the country and the final decision to revise primary annual $PM_{2.5}$ NAAQS described in section II above. We assessed $PM_{2.5}$ concentration data across a range of values to determine if any changes to the statistical calculations used to evaluate the data quality in the $PM_{2.5}$ network were warranted. This section describes the EPA's assessment, comments received, and the EPA's final decisions on the proposed changes. Other changes in this section include clarifications and other improvements that will facilitate consistency and the operation of quality assurance programs by State, local, and Tribal (SLT) agencies nationwide.

a. Quality System Requirements

The EPA reconsidered the appendix A, section 2.3.1.1 goal for acceptable measurement uncertainty (88 FR 5665, January 27, 2023) for automated and manual $PM_{2.5}$ methods for total bias. The existing total bias goal is an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and ±10 percent for total bias. The intent of the proposal was to investigate if this bias goal is still realistic given updated precision and bias statistic. The EPA received one comment that bias reevaluation may be premature, since the final NAAQS standard had not yet been determined at the time of the proposal. The EPA acknowledges this comment but clarifies that the proposed new bias statistic was evaluated at a range of levels including the range of proposed $PM_{2.5}$ standards in the technical memorandum, ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.'' [181] Considering the

[181] Noah, G. (2023). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for

Continued

justification in the technical memorandum and the lack of adverse comments regarding this part of the proposal, the EPA is retaining the appendix A, section 2.3.1.1, goal for acceptable measurement uncertainty for automated and manual $PM_{2.5}$ methods for total bias.

The EPA also proposed to update and clarify ambient air monitoring requirements found in 40 CFR part 58, appendix A, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air Protocol Gas Verification Program (PGVP) (88 FR 5665, January 27, 2023). The EPA proposed to revise appendix A to clarify that in order to participate in the Ambient Air PGVP, producers of Protocol Gases must adhere to the requirements of 40 CFR 75.21(g), and only regulatory ambient air monitoring programs may submit cylinders for assay verification to the EPA Ambient Air PGVP. The EPA received mixed comments in support of and in opposition to this proposed revision. The sole commenter opposing the proposed revision indicated that the proposed PGVP requirements would be additional and is concerned with an increased resource burden. But the EPA responds that the PGVP requirements that were proposed to be added are consistent with the existing PGVP requirements in 40 CFR 75.21(g), and PGVP has been defined as a regulatory requirement since 2016 (81 FR 17263, March 28, 2016), so the proposed part 58 changes are not ''additional'' to existing regulations. After consideration of the comments, the EPA is finalizing the update and clarification of ambient air monitoring requirements found in appendix A, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air PGVP as proposed.

b. Measurement Quality Check Requirements

The EPA proposed to remove section 3.1.2.2 from appendix A, which allows NO_2 compressed gas standards to be used to generate audit standards (88 FR 5665, January 27, 2023). The EPA received one comment supporting this change. As a result of the comment received and other general supportive comments regarding quality assurance, the EPA is finalizing the removal of section 3.1.2.2 from appendix A as proposed.

The EPA proposed to revise the requirement in Appendix A, section 3.1.3.3 changing the National Performance Audit Program (NPAP) requirement for annual verification of gaseous standards to the ORD-recommended certification periods identified in Table 2–3 of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (appendix A, section 6.0(4)) (88 FR 5665). The EPA received one comment supporting this change. As a result of the comment received and other general supportive comments regarding quality assurance, the EPA is finalizing the updated NPAP gaseous certification requirement in section 3.1.3.3 as proposed.

The EPA proposed to adjust the minimum value required by appendix A, section 3.2.4, to be considered valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ (88 FR 5665, January 27, 2023). The EPA received comments in support and against the change. In the only opposing comment, the commenter expressed concern that the method detection limit (MDL) for $PM_{2.5}$ is 2 $\mu g/m^3$. The commenter also indicated that the MDL ''typically has minimal value per the definition of the MDL.'' 40 CFR part 50, appendix L states, ''The lower detection limit of the mass concentration measurement range is estimated to be approximately 2 $\mu g/m^3$, based on noted mass changes in field blanks in conjunction with the 24 m^3 nominal total air sample volume specified for the 24-hour sample.'' The EPA notes that field blanks currently average less than 10 µg nationally, and when divided by the 24 m^3 nominal total air sample volume specified for a 24-hour sample, the result is 0.4 $\mu g/m^3$. The appendix L MDL referenced by the commenter was part of the 1997 PM NAAQS rulemaking (62 FR 38652, July 18, 1997); current data shows that the MDL is substantially lower than the EPA's original estimate. After review of the comments, and in consideration of the recently calculated detection limit for the $PM_{2.5}$ FRM that is substantially lower than our original estimate,[182] the EPA is finalizing the revised minimum value for valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ in appendix A, section 3.2.4 as proposed.

c. Calculations for Data Quality Assessments

The EPA proposed to change Equations 6 and 7 of appendix A, section 4.2.1 that are used to calculate the *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$ and Pb* (88 FR 5666, January 27, 2023). The proposed new statistics are designed to address the high imprecision values that result from using these calculations to compare low concentrations that are now more routinely observed in the networks. The EPA received several comments in support of this change in general, but some commenters indicated that they believed there was an error in the new calculation that may result in high imprecision from the calculation of the equation. The EPA reviewed the technical memorandum and confirmed that a multiplier of 100 was unintentionally left in the proposed relative difference equation, Equation 6. Also, equation 6 was corrected from a normalized percent difference to a normalized relative percent difference that is appropriate for comparing collocated pairs at low concentrations. The technical memorandum titled ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network'' has been amended to correct the error and is included in the docket for this action.[183]

Equation 6 as proposed at 88 FR 5666 (January 27, 2023) was:

Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

[182] See the EPA's $PM_{2.5}$ Data Quality Dashboard available at *https://sti-r-shiny.shinyapps.io/QVA_Dashboard/.*

[183] Noah, G. (2023). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

$$s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

And the corrected Equation 6 is:

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i - Y_i)/2}}$$

Equation 7 is below and is unchanged.

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - (\sum_{i=1}^{k} t_i)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

As a result of the positive comments received and the correction to the equation made in response to some comments, the EPA is finalizing the updated Equation 6 as described and is finalizing Equation 7 as proposed for the calculation of the *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$, and Pb* in section 4.2.1.

The EPA proposed to update the appendix A, section 4.2.5, Equation 8, calculation for the Performance Evaluation Program Bias Estimate for $PM_{2.5}$ (88 FR 5666–67, January 27, 2023). Because average ambient PM concentrations across the nation have steadily declined since the promulgation of the $PM_{2.5}$ standard, the EPA proposed to replace the current percent difference equation with a relative difference equation. The EPA received several comments in support of this change in general, but some commenters identified a potential error in the new calculation that resulted in an artificially high estimate, which they do not support. The EPA reviewed the technical memorandum and discovered that a multiplier of 100 was left in the new relative difference equation used in the bias equation. The technical memorandum, ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network'' has been amended to correct the error and is included in the docket.[184] The proposed Equation 8 proposed at 88 FR 5667 (January 27, 2023) was:

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

and the corrected Equation 8 is:

$$100 \times \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}}$$

As a result of the supportive comments received and the correction to the equation in response to some comments, the EPA is updating and finalizing Equation 8 as described for the calculation for the Performance Evaluation Program Bias Estimate for $PM_{2.5}$, in section 4.2.5.

d. References

The EPA proposed to update the references and hyperlinks in appendix A, section 6 (88 FR 5667, January 27, 2023) to provide accuracy in identifying and locating essential supporting documentation and delete references to historical documents that do not represent current practices. The EPA received only favorable comments, and as a result, the EPA is finalizing the updated the references and hyperlinks in appendix A, section 6, as proposed.

The EPA also proposed to add a footnote to Table A–1 of part 58, appendix A—Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant Monitors (88 FR 5669, January 27, 2023). The proposed footnote clarifies the allowable time (*i.e.,* every two weeks, once a month, once a quarter, once every six months, or distributed over all four quarters depending on the check) between checks and encourages monitoring organizations to perform data assessments at regular intervals. The EPA received two comments regarding this proposed footnote. One commenter indicated that this change is inconsistent with the QA Handbook for Air Pollution Measurement Systems: ''Volume II: Ambient Air Quality Monitoring Program QA Handbook.'' The EPA agrees with the commenter; because the QA Handbook is guidance,

[184] Noah, G. (2023). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

the EPA will revise it after this action is finalized to be consistent with the updated CFR provision. Another commenter does not support the addition of the footnote due to concerns about limiting flexibility. In response, the EPA reiterates that the proposed revision is intended to clarify intent and does not make any changes to the required frequencies or acceptance criteria for data assessment. A ''weight of evidence'' narrative is still found in 40 CFR part 58, appendix A, section 1.2.3. As a result of the comments received and the rationale discussed above, the EPA is finalizing the addition of the new footnote to Table A–1 of part 58, appendix A—Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant Monitors as proposed.

2. Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring

The EPA proposed to revise appendix B, Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring (88 FR 5667, January 27, 2023), in parallel to the proposal to revise appendix A. Thus, this section of the proposal included similar detail and proposed revisions related to evaluating quality system statistical calculations for $PM_{2.5}$, clarifications and other improvements that would facilitate consistency and the operation of quality assurance programs for PSD by SLT agencies nationwide.

a. Quality System Requirements

The EPA reconsidered the goal in appendix B, section 2.3.1.1 for acceptable measurement uncertainty for automated and manual $PM_{2.5}$ methods for total bias (88 FR 5668, January 27, 2023).[185] The current total bias goal is an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and ±10 percent for total bias. The EPA's intent was to investigate if this goal is still realistic given updated precision and bias statistics. The EPA received one comment that bias reevaluation may be premature, since the final NAAQS standard had not yet been determined at the time of the proposal. The EPA acknowledges this comment but clarifies that the proposed new bias statistic was evaluated at a range of levels including the proposed range of $PM_{2.5}$ standards in the technical memorandum, ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.'' [186] Considering the justification in the technical memorandum and the lack of adverse comments regarding the substantive proposal, the EPA is retaining the appendix B, section 2.3.1.1, goal for acceptable measurement uncertainty for automated and manual $PM_{2.5}$ methods for total bias.

The EPA also proposed to update and clarify ambient air monitoring requirements found in 40 CFR part 58, appendix B, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air PGVP (88 FR 5668, January 27, 2023). The EPA proposed to revise appendix B to clarify that in order to participate in the Ambient Air PGVP, producers of Protocol Gases must adhere to the requirements of 40 CFR 75.21(g), and only regulatory ambient air monitoring programs may submit cylinders for assay verification to the EPA Ambient Air PGVP. The EPA received comments in support of and in opposition to this proposed revision. The commenter opposing the revision indicated that the proposed PGVP requirements would be additional and is concerned with an increased resource burden. However, the EPA disagrees with the commenter because that the proposed PGVP requirements are consistent with the existing PGVP requirements in 40 CFR 75.21(g). PGVP has been defined as a regulatory requirement since 2016 (81 FR 17263, March 28, 2016), so the proposed part 58 changes are not ''additional'' to existing regulations. After consideration of the comments, the EPA is finalizing the update and clarification of ambient air monitoring requirements found in appendix B, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air PGVP as proposed.

b. Measurement Quality Check Requirements

The EPA proposed to remove section 3.1.2.2 from appendix B, which allows NO_2 compressed gas standards to be used to generate audit standards (88 FR 5668, January 27, 2023). The EPA received one comment supporting this change. As a result of the comment received and other general supportive comments regarding quality assurance, the EPA is finalizing the removal of section 3.1.2.2 from appendix B as proposed.

The EPA proposed to revise the requirement in Appendix B, section 3.1.3.3 changing the National Performance Audit Program (NPAP) requirement for annual verification of gaseous standards to the ORD-recommended certification periods identified in Table 2–3 of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (appendix B, section 6.0(4)) (88 FR 5668, January 27, 2023). The EPA received one comment supporting this change. As a result of the comment received and other general supportive comments regarding quality assurance, the EPA is finalizing the updated NPAP gaseous certification requirement in section 3.1.3.3 as proposed.

The EPA proposed to adjust the minimum value required by appendix B, section 3.2.4, to be considered valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ (88 FR 5668, January 27, 2023). The EPA received comments in support and against the change. In the only opposing comment, the commenter expressed concern that the method detection limit (MDL) for $PM_{2.5}$ is 2 $\mu g/m^3$. The commenter also indicated that the MDL ''typically has minimal value per the definition of the MDL.'' 40 CFR part 50, appendix L states, ''The lower detection limit of the mass concentration measurement range is estimated to be approximately 2 $\mu g/m^3$, based on noted mass changes in field blanks in conjunction with the 24 m^3 nominal total air sample volume specified for the 24-hour sample''. The EPA notes that field blanks currently average less than 10 µg nationally, and when divided by the 24 m^3 nominal total air sample volume specified for a 24-hour sample, the result is 0.4 $\mu g/m^3$. The appendix L MDL referenced by the commenter was part of the 1997 PM NAAQS rulemaking more than 20 years ago (62 FR 38652, July 18, 1997); current data shows that the MDL is substantially lower than EPA's original estimate. After review of the comments, and in consideration of the recently calculated

[185] In the proposal, in section VII.C.2 Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring (88 FR 5667–69), the EPA inadvertently referred to ''appendix A'' in the section rather than the correct ''appendix B.'' The EPA's intent to have proposed changes to appendix B on these pages is made clear by the section header, the Table of Contents on page 5559, and the proposed regulatory text for appendix B on pages 5707–08. See, *e.g.,* id. at p.5668 (preamble erroneously states that the EPA proposed to change appendix A, section 2.6.1); id. at p.5668 (preamble erroneously states that the EPA proposed to adjust the minimum value required by appendix A, section 3.2.4).

[186] Noah, G. (2023). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

detection limit for the $PM_{2.5}$ FRM that is substantially lower than our original estimate, the EPA is revising the minimum value for valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ in appendix B, section 3.2.4 as proposed.

c. Calculations for Data Quality Assessments

The EPA proposed to change Equations 6 and 7 of appendix B, section 4.2.1 used for calculating the *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$ and Pb* (88 FR 5707, January 27, 2023). These new statistics are designed to address the high imprecision values that result from using these calculations to compare low concentrations that are now more routinely observed in the networks. The EPA received several comments in support of this change in general, but a couple commenters indicated that there could be an error in the new calculation that resulted in high imprecision from the calculation of the equation. The EPA reviewed the technical memorandum and discovered that a multiplier of 100 was unintentionally left in the proposed relative difference equation, Equation 6. Also, equation 6 was corrected from a normalized percent difference to a normalized relative percent difference that is appropriate for comparing collocated pairs at low concentrations. The technical memorandum titled ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network'' was amended to correct the error and is included in the docket.[187]

Equation 6 in the proposal (88 FR 5668, January 27, 2023) was:

$$s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

And the corrected Equation 6 is:

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i - Y_i)/2}}$$

Equation 7 is below and is unchanged.

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - (\sum_{i=1}^{k} t_i)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

As a result of the positive comments received and the correction to the equation made in response to those comments, the EPA is finalizing the update to Equation 6 and retaining Equation 7 as proposed for the calculation of the *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$ and Pb* in section 4.2.1.

The EPA proposed to update the appendix B, section 4.2.5, Equation 8, calculation for the Performance Evaluation Program Bias Estimate for $PM_{2.5}$ (88 FR 5668–59, January 27, 2023). Because average ambient PM concentrations across the nation have steadily declined since the promulgation of the $PM_{2.5}$ standard, the EPA proposed to replace the current percent difference equation with a relative difference equation. The EPA received several comments in support of this change in general, but some commenters identified a potential error in the new calculation that resulted in an artificially high estimate, which they do not support. The EPA reviewed the technical memorandum and discovered that a multiplier of 100 was left in the new relative difference equation used in the bias equation. The technical memorandum, ''Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network'' has been amended to correct the error and is included in the docket. The proposed Equation 8 (88 FR 5669, January 27, 2023) was:

[187] Noah, G. (2023). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

and the corrected Equation 8 is:

$$100 \times \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}}$$

As a result of the supportive comments received and the correction to the equation in response to some comments, the EPA is updating and finalizing Equation 8 as described for the calculation for the Performance Evaluation Program Bias Estimate for $PM_{2.5}$, in section 4.2.5.

d. References

The EPA proposed to update the references and hyperlinks in appendix B, section 6 (88 FR 5669, January 27, 2023) to provide accuracy in identifying and locating essential supporting documentation and delete references to historical documents that do not represent current practices. The EPA received only favorable comments, and as a result, the EPA is finalizing the updated the references and hyperlinks in appendix B, section 6, as proposed.

The EPA also proposed to add a footnote to Table B–1 of part 58, appendix B—Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant PSD Monitors (88 FR 5669, January 27, 2023). The proposed footnote clarifies the allowable time (*i.e.,* every two weeks, once a month, once a quarter, once every six months, or distributed over all four quarters depending on the check) between checks and encourages monitoring organizations to perform data assessments at regular intervals. The EPA received two comments regarding this proposal. One commenter indicated that this change is inconsistent with the QA Handbook. The EPA agrees with the commenter; because the QA Handbook is guidance, the EPA will revise it after this action is finalized to be consistent with the updated CFR provision. Another commenter does not support the addition of the footnote due to concerns about limiting flexibility. In response, the EPA reiterates that the proposed revision is intended to clarify intent and does not make any changes to the required frequencies or acceptance criteria for data assessment. A ''weight of evidence'' narrative is still found in 40 CFR part 58, appendix B, section 1.2.3. As a result of the comments received and the rationale discussed above, the EPA is adding the new footnote to Table B–1 of part 58, appendix B—Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant PSD Monitors as proposed.

3. Amendments to PM Ambient Air Quality Methodology

a. Revoking Approved Regional Methods (ARMs)

The EPA proposed to remove provisions for approval and use of Approved Regional Methods (ARMs) throughout parts 50 and 58 of the CFR (88 FR 5669, January 27, 2023). ARMs are continuous $PM_{2.5}$ methods that have been approved specifically within a State or local air agency monitoring network for purposes of comparison to the NAAQS and to meet other monitoring objectives. Currently, there are no approved ARMs. There are, however, more than a dozen approved Federal Equivalent Methods (FEMs) for $PM_{2.5}$. These approved FEMs are eligible for comparison to the NAAQS and to meet other monitoring objectives.

The EPA received comments from multiple State air programs in support of the proposal to remove provisions for approval and use of ARMs. One commenter cites that there are multiple FEMs available for monitoring agencies to work with and that the agency was never able to get a candidate ARM to meet the requirements for approval. With the availability of multiple FEMs that now work in the monitoring agency's network, the commenting agency does not anticipate the need to ever pursue an ARM in the future and, therefore, suggests that the ARM provision is no longer needed. Another commenter strongly supported the proposed changes to remove the ARM provisions. The EPA also received comments from a few agencies that supported retaining the ARM provisions instead. One commenter cited the need to consider the rapid advancement of various new technologies and that, in some cases, approved continuous FEMs may have shortcomings, meaning that losing the ability to propose an ARM in the future may limit useful alternative options to monitoring agencies. Another commenter suggested that the removal of the ARM would take away the ability and right to use locally derived correction factors.

After considering the comments for and against removing the provisions for ARMs, the EPA believes it is most appropriate to remove the ARM provisions. As described in the proposal, when the EPA first proposed the process for approving and using ARMs, there were no continuous FEMs approved. There are now over a dozen approved $PM_{2.5}$ continuous FEMs and no approved ARMs. Therefore, the EPA is finalizing the removal of ARMs throughout 40 CFR parts 50 and 58 as proposed.

b. Calibration of PM Federal Equivalent Methods (FEMs)

The EPA proposed to modify its specifications for PM FEMs in appendix C to Part 58 (88 FR 5670–73, January 27, 2023). Specifically, the EPA proposed that valid State, local, and Tribal (SLT) air monitoring data from Federal Reference Methods (FRMs) generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs. This approach, initiated by instrument manufacturers, would be implemented as a national solution in factory calibrations of approved FEMs through a firmware update. This could apply to any PM FEM methods (*i.e.,* PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$).

The EPA proposed this modification because there are some approved PM FEMs that are not currently meeting bias measurement quality objectives (MQOs) when evaluating data nationally as described in the 2022 PA (U.S. EPA, 2022b, section 2.2.3.1), meaning that an update to factory calibrations may be appropriate; however, there is no clearly defined process to update the calibration of FEMs. While there are several types of data available to use as the reference for such updates (*e.g.,* routinely operated FRMs, audit program FRMs, and chemical speciation sampler

data), we proposed to use routinely operated SLT FRMs as the basis of comparison upon which to calibrate FEMs. The goal of updating factory calibrations would be to increase the number of routinely operating FEMs meeting bias MQOs across the networks in which they are operated. While there are other approaches that could improve data comparability between PM FEMs and collocated FRMs, the EPA believes that the proposed modification to calibrate PM FEMs represents the most reliable approach to update FEM factory calibrations, since the existing FRM network data that meet MQOs would be used to set updated factory calibrations.

While the Agency proposed to add this language to more expressly define a process to update factory calibrations of approved PM FEMs, the EPA believes that the existing rules for updating approved FRMs and FEMs found at 40 CFR 53.14 may also continue to be utilized for this purpose, as appropriate. 40 CFR 53.14 allows instrument manufactures to submit to the EPA a ''Modification of a reference or equivalent method.'' Submitting a modification request may be appropriate to ensure an approved FEM continues to meet 40 CFR 53.9, ''Conditions of designation.'' Specifically, 40 CFR 53.9(c) requires that, ''Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10–2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).'' Thus, instrument manufacturers are encouraged to seek improvements to their approved FEM methods as needed to continue to meet data quality needs as operated across the network.

There are several technical components to EPA's proposed modification, including: the reference data to be used in the calibrations; implementing as a national solution in factory calibrations of approved FEMs through firmware updates; application to any PM FEM methods (*i.e.,* PM_{10}, $PM_{2.5}$, and $PM_{10–2.5}$); the appropriate range of data to be used to develop and test new factory calibrations, from just the most representative concentrations up to all available concentrations; the representative set of geographic locations that can be used; whether outliers may be included or not included; that new factory calibrations should be developed using data from at least 2 years and tested on data from a separate year or years; that updates to factory calibrations can occur as often as needed; that calibrations should be evaluated by monitoring agencies as part of routine data assessments, *e.g.,* during certification of data and 5-year assessments; the EPA's recognition that only data from existing operating sites is available; and finally, that an updated factory calibration does not have to work with the original field study data submitted that led to the original FEM designation.

With the proposed modification, the EPA solicited input on these technical issues as well as the overall approach and any alternatives that could lead to more sites meeting the bias MQO with automated FEMs, especially for those sites that are near the level of the primary annual $PM_{2.5}$ NAAQS, as proposed to be revised in section II above. In response, the EPA received comments from about two dozen entities, most of which were SLT air programs or Multi-Jurisdictional Organizations (MJOs) comprised of these entities.

Overall, there was broad and strong support from a majority of commenters for the proposed requirement to use FRM data generated in routine networks and submitted to the EPA to update factory calibrations included as part of approved FEMs. There were a smaller number of critical comments on the proposed process as well as some commentors that supported the proposed requirement but also provided additional suggestions for the EPA's consideration. Below, we address each of the areas on which the EPA requested comment regarding the calibration of PM FEMs, as well as a few additional areas where multiple commenters offered input on other areas related to our proposal.

A majority of the commenters on the proposed PM FEM calibration process support the process to use valid State, local, and Tribal FRM data generated in routine networks and submitted to the EPA to improve the PM concentration measurement performance of approved FEMs. Some commenters suggested that this action is needed to ensure that data reported from FRMs and FEMs are comparable and correction methods applied to data from FEM monitors are defensible across the national PM monitoring network. Others stated that they agree with the EPA that this is a critical step in the right direction to account for the discrepancies between $PM_{2.5}$ FRM data and $PM_{2.5}$ FEM data. Some commented that applying corrections includes a recognition that, while different measurement principles may produce differences in the resulting data, having an approach that minimizes bias is extremely important. Finally, some stated their belief that a correction factor is necessary to preserve data integrity with the FRM.

The EPA also received comments suggesting ways that the PM FEM correction could be performed, including through detailed analysis of data; by having PM FEM instrument manufacturers evaluate nationally available valid FRM data to update factory calibrations; and, by having the instrument manufacturers implement calibration adjustments at the factory.

The EPA also received supportive comments on the PM FEMs calibration relating to comparability to the NAAQS. For example, a commenter stated that it is important to ensure bias MQOs are met for FEMs run at sites potentially affected by revised standards as well as the need to accurately designate areas as attaining or not attaining the NAAQS. There were comments supporting the correction of PM FEM data as helping the EPA and SLT monitoring programs continue to evolve toward more automated methods. For example, one commenter appreciates the EPA's support for the ongoing move from filter-based $PM_{2.5}$ FRMs to use of continuous FEMs, stating that they concur with the EPA's assessment that there is monitoring bias between FRMs and FEMs, and commending EPA for recognizing ongoing data quality issues for FEMs and for taking action to improve these issues in collaboration with instrument manufacturers and SLT agencies.

A small number of commenters were critical of the proposed FEM calibration approach. One commenter noted that EPA should further examine the handling of FEM $PM_{2.5}$ data when used for comparison to the NAAQS. In response, we note that monitoring agencies and the EPA will continue to examine the comparability and use of FEM data used in comparison to the NAAQS. Another commenter suggested that the calibration process for a designated PM monitor should not be altered following Class III designation approval. The EPA disagrees as we believe it is appropriate for FEMs to be calibrated with routinely operated FRMs, because doing so is an efficient way to work towards FEM data meeting the bias MQO across the networks in which the FEMs are currently being operated. Also, having continuous PM FEMs meeting bias MQOs allows the use of the data in a variety of other ways that manually operated FRMs samplers cannot support. Another commenter stated that, if a particular FEM designated make or model of

instruments fails to meet MQOs, then that make or model should be removed from the designations altogether. The EPA agrees and clarifies that the modification would not prevent removal of FEM designation from a make or model of instrument under the existing 40 CFR 53.11—Cancellation of reference or equivalent method designation. This may be appropriate if there are no other solutions to improve the method such that it achieves bias MQOs.

A few commenters provided specific recommendations for how the regulatory language could be improved. These included comments that the new regulatory language proposed for 40 CFR part 58, appendix C, section 2.2 must ensure consistency and transparency when requesting changes to the factory calibration; that the EPA should incorporate binding regulatory language in 40 CFR part 58, appendix C, section 2.2 (*i.e.,* it currently lacks ''shall'' or ''must'') to ensure the language is not open to inconsistency and does not provide unique deference to instrument manufacturers without a mechanism for transparent communication of the changes being made and the supporting technical analysis. A commenter also requested that the EPA define the core requirements needed to ensure all requests for updating factory calibrations are required to follow the same process, using data of the same known quality, and evaluating the effectiveness of the resulting correction factors consistently.

In response to these comments, while the EPA agrees that the proposed regulatory language for 40 CFR part 58, appendix C, section 2.2 must ensure consistency and transparency when entities request changes to factory calibrations, the EPA disagrees that the regulations cannot also provide some flexibility. For example, we believe that a degree of flexibility is appropriate regarding whether outliers in the data to be used for factory calibration should or should not be included, the range of data to be included, and in utilizing collocated FRM and FEM data for updated calibrations from a representative set of geographic areas in which it is produced. The EPA believes that the proposal defined the core requirements needed to ensure all requests for updating FEM factory calibrations will follow the same process, using data of the same known quality and evaluating the effectiveness of the resulting correction factors consistently.

In its proposal, the EPA identified that while there are several types of data available to use as the reference for FEM calibration updates, including data from routinely operated FRMs, audit program FRMs, and $PM_{2.5}$ chemical speciation samplers, the EPA proposed to use routinely operated State, local, and Tribal FRMs as the basis of comparison upon which to calibrate FEMs (88 FR 5670–71, January 27, 2023). Importantly, routine SLT agency FRM data form the largest portion of the monitored air quality data used in epidemiologic studies that are being used to inform proposed decisions regarding the adequacy of the public health protection afforded by the primary $PM_{2.5}$ NAAQS, as discussed in section II above.

Overall, there was broad and strong support for utilizing collocated FRM data from routine SLT networks to provide calibrations of the continuous FEMs. For example, several commenters agree that valid SLT air monitoring data generated in routine networks and submitted to the EPA will improve the PM concentration measurement performance of approved FEMs. Another commenter provided support for PM FEM instrument manufacturers to evaluate nationally available valid FRM data as well as other data sets such as the performance evaluation audit program to update factory calibrations. The EPA believes that the routinely operated PM FRMs represent the best and largest source of data to calibrate continuous PM FEMs, and that performance evaluation audit program data should be kept independent of the calibration process. This will mean that assessments of the routine monitoring operations, including both the FRM and any future updated PM FEMs, will appropriately remain independent in evaluating whether updated methods are meeting bias MQOs. The EPA is, therefore, finalizing its approach to use routinely operated SLT FRMs as the basis of comparison upon which to calibrate continuous PM FEMs as proposed.

Regarding the EPA's proposed requirement to utilize factory calibrations (88 FR 5670–71, January 27, 2023), several commenters agreed that factory calibrations provide the best option to improve PM FEMs. For example, one commenter stated that the correction factors are necessary to preserve data integrity with the FRM, and they support the proposal that the approach be initiated by instrument manufacturers and implemented as a national solution through firmware updates.

Regarding the proposed requirement that calibrations be initiated by instrument manufacturers (88 FR 5671, January 27, 2023), most commenters were supportive of the proposed approach that recalibration of FEM PM instruments be initiated by instrument manufacturers. For example, one commenter stated they support allowing instrument companies submit improvements to their existing FEMs, as vendors should be encouraged to improve their methods. Another commenter noted that having a methodology initiated by the manufacturer will have nationwide consistency. A few of commenters recommended that SLT air agencies should have the additional ability to petition the EPA Administrator to initiate factory calibrations of FEMs to better meet MQOs when data collected by their agencies indicate disparities, because the monitoring agencies are responsible for the quality of the data from the specific makes and models of instrumentation used in their networks. While the EPA believes that, in most cases, the instrument companies should be the ones to initiate the process for calibration of FEMs to routinely operated FRMs, we agree with the commenters who suggested that other options should be available, including allowing monitoring agencies or MJOs to work independently or together to pursue improvements to designated FEMs. However, the EPA believes that any such improvements initiated by monitoring agencies or MJOs should still be facilitated through the responsible instrument company. Also, any such effort to improve data quality should be employed across all the networks in which the methods are operated and not limited to the networks operated by the agency(s) pursuing such improvements.

Regarding how frequently factory calibrations should be updated, our proposal identified that it would be most appropriate to not define a specific time period for updates; rather, updates should be based on whether or not quality data is being produced across a given network (88 FR 5672, January 27, 2023). Regarding this issue, one commenter recommended that instrument manufacturers be required to evaluate and, if necessary, adjust PM FEMs factory calibrations on an ongoing basis at regular intervals. The EPA notes that while it does not have the authority to require instrument companies to evaluate the quality of data from operating FEMs under 40 CFR part 58, the EPA does routinely participate in conferences and workshops and makes assessments of data quality specific to instrument makes and models publicly available. The EPA also regularly summarizes relevant FRM and FEM data

quality in documents such as the 2022 PA (U.S. EPA, 2022b). Therefore, consistent with the proposal, we are not finalizing any specifics regarding how frequently factory calibrations should be updated but commit to continue to routinely provide information to SLT agencies regarding FEM data quality.

The EPA proposed that the calibration of FEMs could apply to any of the PM FEM method indicators (*i.e.,* PM_{10}, $PM_{2.5}$, and $PM_{10–2.5}$) (88 FR 5670, January 27, 2023). The EPA received only supportive comments. All comments that included a discussion of three PM metrics support their inclusion for calibration of PM FEMs. Therefore, the EPA is finalizing the inclusion of all three PM indicators (*i.e.,* PM_{10}, $PM_{2.5}$, and $PM_{10–2.5}$) as proposed.

The EPA proposed that either all data available or a range of data up to 125% of the 24-hour NAAQS for the PM indicator of interest may be used to establish new factory calibrations, (88 FR 5671–73, January 27, 2023). The EPA received many comments supportive of the proposal and one comment offering a different approach on the range of data to use. One commenter recommends that the EPA should consider using all ''validated'' data because how these instruments behave under normal operating ranges may be just as important as how they behave when monitoring conditions are low or elevated, and that the full range of data should be used when determining the appropriate level of the standard, just as the full range of data is used in determining if an area is attaining the standard. In response to this comment, the EPA believes that making allowances for some flexibilities will increase the likelihood of instrument companies pursuing such improvements. Also, even though there is flexibility, the EPA will still be able to evaluate the appropriateness of a range of concentration data included as part of each application submitted. Also, the EPA notes that in certain circumstances, States do petition the EPA to set aside data under the Exceptional Events Rule (§ 50.14, ''Treatment of air quality monitoring data influenced by exceptional events''). Where approved, exceptional event data are set aside from use in regulatory decisions. Thus, there is a process to set aside certain high concentration data for certain purposes. Therefore, the EPA is finalizing the provision that factory calibrations may be based on a range of valid data as proposed.

The EPA solicited comment on the representative set of geographic locations to use in the calibration of FEMs compared to collocated FEMs (88 FR 5671, January 27, 2023). Most commenters were supportive of the approach of using representative sites in SLT networks from across the country. For example, several commenters provided their support for PM FEM instrument manufacturers to evaluate nationally available valid FRM data to update factory calibrations. Commenters disagreeing with a national geographic approach preferred to allow local solutions to correct data. For example, one commenter suggested having a local or regional option because PM instruments are impacted by, and respond differently to, a variety of local factors, including relative humidity, temperature, concentration levels, and particle composition. The EPA agrees that there are challenges in the response of PM FEMs to a variety of local factors; however, this can be true of many methods and are not specific to PM FEMs and, therefore, does not provide a reason to reject this approach in this instance. Another commenter stated that the proposed national correction factor is a ''flawed concept,'' suggesting that it is ''widely understood throughout the monitoring community that monitors perform best with a local correction factor.'' This commentor offered no record or citation supporting this point. The EPA counters that while monitoring agencies may statistically correct data from a PM continuous monitor for AQI purposes (40 CFR part 58, appendix G), there are both examples of well performing statistically corrected PM continuous monitors being used for AQI purposes; however, without proper attention and updates, there are also examples of poorly performing ones. Finally, another commenter believes that a national correction factor cannot possibly incorporate data to represent all the scenarios across the nation that have an impact on monitor performance and data quality. Although the EPA agrees that there are a variety of local scenarios that could affect monitor performance, the overall benefits of having nationally consistent measurement of PM concentrations and national calibration of data outweigh the potential advantages of locally specific calibrations.

Several commenters also disagreed with using local and regional calibrations of data, including some monitoring agencies that asserted being unable to reinvest in the operation of FRMs that would be required to locally calibrate their own PM FEMs. Further, every approved PM FEM method designated today is effectively calibrated through demonstration of field testing in the areas in which it was required to be tested (40 CFR 53.35(b)(1)). Moreover, the EPA proposed to require instrument manufacturers to demonstrate that they can improve the number of sites meeting bias MQOs by initiating a recalibration of an FEM. Thus, the use of a national set of sites where the methods are operated is essentially a fine-tuning of the PM FEMs performance across all sites where it is used.

After considering all the comments received, the EPA believes it is appropriate to finalize as proposed with a representative set geographic locations at SLT sites to calibrate PM FEMs. Identification of such sites would be made by the applicant of the planned updated calibration, subject to EPA approval, and submitted to the EPA in accordance with the requirements and application instructions in 40 CFR part 58, appendix C, sections 2.2 and 2.7. The EPA encourages early communication between an applicant seeking a method update and the EPA to facilitate the most appropriate sites are included in any updated application of the methods calibration.

The EPA proposed that instrument companies may, but are not required to, check for and exclude any potential outliers that may exist in the validated State, local, and Tribal agency network data available from AQS that would be used to establish new factory calibrations. The EPA received two comments regarding potential outlier approaches. One commenter disagreed with the proposed approach and instead recommended the use of all ''validated'' data, because how these instruments behave under normal operating ranges may be just as important as how they behave when monitoring conditions are low or elevated. The EPA acknowledges this point; however, the proposal on outliers allows flexibility in using standard outlier tests if needed to include or exclude such data as part of the calibration process. Ultimately, the true test of success for an updated method calibration will be that a higher number of sites are meeting bias MQOs in the areas in which the method is used, which will include all routine valid data including any potential outliers. Another commenter asserted concerns with the ability of instrument manufacturers to analyze data within individual monitoring agencies. The EPA disagrees with the commenter because decisions whether to include or exclude outliers should be flexible and made on a case-by-case basis. Moreover, the expected substantially larger dataset from routinely operated collocated FRMs and FEMs compared to what was

used in the original FEM designation testing (§ 53.35 Test procedure for Class II and Class III methods for $PM_{2.5}$ and $PM_{10–2.5}$) will minimize the effect of any potential outliers.

In contrast to these two comments, the EPA received many comments supportive of the proposed outlier approach overall. Therefore, the EPA is finalizing this part of the proposal that instrument companies may, but are not required to, check for and exclude any potential outliers that may exist in the validated State, local, and Tribal agency network data available from AQS that would be used to establish new factory calibrations.

Several commenters offered input on statistical criteria and initial testing requirements for approval of candidate PM FEMs and the role of instrument manufacturers in this process. The EPA did not propose any changes related to these issues; however, these comments have been considered below.

One commenter suggested that data quality objectives, bias, and precision estimators for different monitoring methods should be based on averages at both national and regional levels for purposes of comparison. Another commenter asked to strengthen the criteria for Class 3 Equivalency standards for candidate PM instrumentation. On testing requirements, one commenter recommended that the EPA consider updating the 40 CFR part 53 process for approving FEMs so that the testing process more closely reflects the regulatory deployment and data handling that generates NAAQS-comparable data. Another commenter asked that the results from ''summer'' and ''winter'' field evaluations not be averaged together because it allows agencies to minimize the error of biased instruments by averaging poor results with data often biased in the other direction. The same commenter also recommended that candidate instruments data sets should not be averaged together as is done currently where data from triplicate instruments are averaged for each day. Another commenter asked that the EPA require FEM field comparability tests in the northwest (*e.g.,* in EPA Region 10) in areas where particulate derived from biomass predominates to ensure that certified instruments will perform reliably in regions influenced by these sources. Related to the different measurement principles and the instrument companies' role in PM FEMs, one commenter noted that FEMs may never align perfectly with the FRMs due to the use of different measurement principles. Another commenter asked that manufacturers of FEM instruments be held accountable for ensuring that they continue to meet FEM criteria, whether through calibration updates and/or follow-up evaluations. Another commenter suggested that instrument manufacturers should be required to further evaluate the FEM monitoring data at defined intervals including, but not limited to, the 2-year and 5-year approval anniversaries.

The EPA did not propose to make modifications to the statistical criteria or testing requirements; however, we did solicit comment on any alternatives that would lead to more sites meeting the bias MQO with automated FEMs, especially for those sites that are near the level of the primary annual $PM_{2.5}$ NAAQS as proposed (88 FR 5672–73, January 27, 2023). While the comments requesting that the statistical criteria be strengthened may have merit, doing so would not address the large inventory of already deployed PM FEMs used throughout the country. Also, without performing a detailed Data Quality Objective (DQO) design process, it is unclear how changing one or more statistical criteria would help improve the number of sites meeting the bias MQO now or in the future. Similarly, while the comments asking for changes to the locations of testing may also have merit, the EPA believes this could be a deterrent for instrument manufactures to seek additional improvements since more testing would be required, at least for candidate methods. Regarding the comment on the different measurement principles, the EPA concurs that different measurement principles may never align perfectly. Also, the EPA notes that the Agency has longstanding goals for acceptable measurement uncertainty of automated and manual $PM_{2.5}$ methods in 40 CFR part 58, appendix A, section 2.3.1.1. Therefore, while having different measurement principles align is useful, meeting the goal for acceptable measurement uncertainty is the objective.

Regarding the comments related to the instrument companies' role in PM FEMs, the EPA notes that FEMs are already required to meet 40 CFR 53.9, ''Conditions of designation.'' Specifically, 40 CFR 53.9(c) requires that, ''Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10–2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).'' The EPA does not have the authority to require instrument manufacturers to further evaluate the FEM monitoring data at defined intervals, including but not limited to the 2-year and 5-year approval anniversaries, as one commenter suggested.

In addition to these few recommendations, the EPA received many comments supportive of the proposal that valid State, local, and Tribal air monitoring data from FRMs generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs; therefore, consistent with the proposal we are not finalizing any updates to the statistical criteria, testing requirements, or requirements on instrument manufactures as proposed.

The EPA proposed that any new factory calibration should be developed using data from at least 2 years and tested on a separate year(s) of data (88 FR 5672, January 27, 2023). Comments on this part of the proposal were generally supportive. One commenter requested that at least a 3-year dataset, rather than the proposed 2 years, be used for a representative design value comparison of the FEM and FRM datasets to be evaluated. Another commenter pointed out that as large a data set as possible should be used, but EPA should not limit it to only data collected by instruments that have operated for more than 2 years.

In response to these comments, the EPA notes the broad support for the proposal as written. Also, the EPA notes that the 2-year period for using data to develop a factory calibration is a minimum, and that more years may be used as appropriate. Therefore, the EPA is finalizing its approach that any new factory calibration should be developed using data from at least 2 years and tested on a separate year(s) of data as proposed.

The EPA proposed several aspects of the FEM calibration on which we did not receive specific comments, including a provision that FEM methods should be evaluated by monitoring agencies as part of routine data assessments, such as during certification of data and 5-year assessments; the fact that the EPA recognizes only data from existing operating sites are available for use in factory calibrations; and recognition that an updated factory calibration does not have to work with the original field study data submitted that led to the designation as an FEM. With the broad general support from commenters summarized above, the EPA is finalizing each of these

individual aspects of the FEM calibration as proposed.

In the proposal, the EPA identified that we should expect a lag between the date when an already designated method is approved with a new factory calibration as an updated method by the EPA and when it can be implemented in the field. The EPA solicited comment on how to approach the data produced during this lag. Commenters provided input not only on how to address data during the lag, but also regarding how to address data already collected prior to a method update that has the potential to be used in regulatory decision making, particularly where such collected data do not meet the bias MQO. In response to this solicitation of comment, there was a consistent recommendation that calibrations of data associated with method updates should be applied to all relevant PM data prior to the EPA using it for designations under a final NAAQS.

While the EPA appreciates these comments and recognizes their support for retroactive data correction, at this time and following this final rule, monitoring agencies should continue to report PM FEM data as measured. This component of this final rule is focused only on revising 40 CFR part 53, appendix C to implement an updated calibration for approved PM FEMs. The issue of how prior and future monitoring data will be used in the implementation of this NAAQS, such as for designations, and for air quality regulatory programs is outside the scope of this rulemaking and will therefore be addressed by the EPA in a subsequent relevant action or actions.

The EPA received comments on whether updates to PM FEM methods should be required to be implemented or there would flexibility in when and if a monitoring agency implemented them. The commenters asked that EPA be flexible in allowing the use of updated method correction factors intended to improve the data comparability between the FRMs and FEMs.

In most cases, the EPA expects that updating the FEMs will result in improved data quality and more sites meeting bias MQOs; however, the EPA is not finalizing an update requirement in this action. Monitoring agencies can assess their data and make decisions on an update based on whether they are meeting the bias MQOs. Such decisions on whether or not to update a method may efficiently be included in those agencies' annual monitoring network plans under 40 CFR 58.10, ''Annual monitoring network plan and periodic assessment,'' which are already subject to EPA Regional office approval. In some circumstances, it is possible the original PM FEM may be revised in a manner where only the updated method has an active approved designation. In these cases, monitoring agencies would need to address updating their PM FEM in a timely manner.

The EPA solicited input on any alternative approaches that could lead to more sites meeting the bias MQO with automated PM FEMs, especially for those sites that are near the level of the primary annual $PM_{2.5}$ NAAQS as proposed to be revised in section II above. A few commentors provided input on potential options for alternative approaches and several others offered input on how a local or regional calibration of an FEM could work. Among alternative approaches, one commenter suggested that manufacturers of FEMs could provide settings that would allow for adjustments to make FEM data more ''FRM-like.'' Another commenter suggested working with the manufacturers of FEM equipment to diagnose the cause of the bias and then to address it appropriately.

The EPA received several comments on how to implement a local or regional calibration of FEMs. One commenter suggested that EPA could allow for SLT agencies to adjust FEM data to be more ''FRM-like'' prior to submitting data to AQS. Another commenter suggested using a rolling 3-month linear regression based on a comparison of FEM data to $PM_{2.5}$ levels measured by a 1-in-6-day FRM. Another commenter recommended that the EPA allow the application of a correction factor that is from an area with a similar climate and other conditions. Another commenter suggested that, for metropolitan statistical areas (MSAs) where the re-calibrated FEMs still do not meet equivalency criteria, monitoring agencies should be able to use the rolling linear regression technique to further calibrate the FEMs within an MSA. Another commenter suggested that developing a simple linear regression could establish the relationship between FEM data and FRM data and be used to adjust the FEM data at each site where they are collocated. Another commenter suggested that averaging the results within a MSA and applying it on an MSA basis with the previous 2 years of data could provide an adjustment method for sites without a collocated FRM. Another commenter identified that a regional correction factor potentially could improve instrument accuracy to biomass sources, which are a large component of PM in many communities.

Among the alternative approaches suggested, having settings that would allow for adjustments to make FEM data more ''FRM-like'' has merit, but assuming this was within a PM FEM itself, it would need to be separately incorporated into each make and model of FEM. If EPA were to pursue this alternative approach, the suggestion could be incorporated into a future regulatory action as a potential condition of designation because, without having the opportunity to thoughtfully consider how every step of such an approach would need to work, including what such requirements would look like and how potential settings adjustments would be made, it is not appropriate for the EPA to require the availability of such settings now, nor would it address the inventory of currently available PM FEMs already operating.

Regarding the suggestion that the EPA and SLTs should work with the manufacturers of FEM equipment to diagnose the cause of any biases and then to address them appropriately, the EPA supports this recommendation, but does not believe a regulatory change is required to allow the monitoring community (EPA and SLTs) to work with instrument manufacturers in this way.

Regarding the several comments on how to implement a local or regional calibration of FEMs, the EPA acknowledges the desire for this flexibility but believes that any such provisions for local or regional calibration of FEMs would need to be thoroughly thought out and proposed for consideration across the monitoring community. While several commenters support such an approach, the EPA also received adverse comments on the potential for local and regional calibration of PM FEMs instead of national. Most of the criticism of local and regional calibration of PM FEMs centered on both the lack of existing operating PM FRMs in commenters' networks and monitoring agencies' inability to staff the higher number of operating FRMs that would have to be collocated with PM FEMs to calibrate. Thus, the commenters that oppose local and regional calibrations of data prefer to utilize the national calibration of FEM data as proposed. Acknowledging all of these viewpoints, the EPA believes that it would not be appropriate to institute such an approach at this time. As discussed throughout this section, this final rule, the EPA is embarking on a new national approach to calibration of FEMs where valid State, local, and

Tribal air monitoring data from FRMs generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs. The EPA and the community of SLT monitoring agencies can further consider other solutions to improving PM FEM methods, including local and regional scale calibration of FEMs, in a future review of the PM NAAQS.

In summary, the EPA is finalizing its proposal to allow valid State, local, and Tribal air monitoring data from PM FRMs and FEMs generated in routine networks and submitted to the EPA to update factory calibrations included as part of approved FEMs (40 CFR part 58, appendix C, sections 2.2 and 2.7). This approach, which will typically be initiated by instrument manufacturers but can also be spurred by monitoring agencies, MJOs of monitoring agencies, and the EPA itself, is to be implemented as a national solution in factory calibrations of approved FEMs through a firmware update, subject to EPA approval. FEM calibrations can apply to any PM FEM methods (*i.e.,* PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$). As part of this process, the EPA is finalizing that a range of data based on the most representative concentrations up to all available concentrations may be used in developing and testing a new factory calibration; that a representative set of geographic locations can be used; that outliers may be included or not included; that a new factory calibration should be developed using data from at least 2 years and tested on a separate year(s) of data; that updates to factory calibrations can occur as often as needed and should be evaluated by monitoring agencies as part of routine data assessments such as during certification of data and 5-year assessments; that the EPA recognizes only data from existing operating sites is available; and that an updated factory calibration does not have to work with the original field study data submitted that led to the designation as an FEM. The EPA is finalizing this approach as proposed with the intention of having more sites meet the bias MQOs with automated PM FEMs.

4. Revisions to the $PM_{2.5}$ Monitoring Network Design Criteria To Address At-Risk Communities

To enhance protection of air quality in communities subject to disproportionate air pollution risk, particularly in light of the proposed range for a revised primary annual $PM_{2.5}$ standard, the EPA proposed to modify the $PM_{2.5}$ monitoring network design criteria to include an environmental justice (EJ) factor that accounts for proximity of at-risk populations (*i.e.,* those identified in the 2019 ISA and ISA Supplement as being at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern), consistent with the statutory requirement that the NAAQS protect the health of at-risk populations (88 FR 5673, January 27, 2023). Specifically, the EPA proposed to modify the existing requirement at 40 CFR part 58, appendix D, section 4.7.1(b)(3)): ''For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality,'' to additionally address at-risk communities with a focus on anticipated exposures from local sources of emissions. The scientific evidence evaluated in the 2019 ISA and ISA Supplement indicates that sub-populations at potentially greater risk from $PM_{2.5}$ exposures include children, lower socioeconomic status (SES) [188] populations, minority populations (particularly Black populations), and people with certain preexisting diseases (particularly cardiovascular disease and asthma). The EPA proposed that communities with relatively higher proportions of sub-populations at greater risk from $PM_{2.5}$ exposure within the jurisdiction of a State or local monitoring agency should be considered ''at-risk communities'' for these purposes.

The $PM_{2.5}$ network design criteria have led to a robust national network of $PM_{2.5}$ monitoring stations. These monitoring stations are largely in Core-Based Statistical Areas (CBSAs) [189] across the country that include many $PM_{2.5}$ monitoring sites in at-risk communities. Many of the epidemiologic studies evaluated in the 2019 ISA and ISA Supplement, including those that provide evidence of disparities in $PM_{2.5}$ exposure and health risk in minority populations and low-SES populations, often use data from these existing $PM_{2.5}$ monitoring sites. However, we anticipate that with the more protective annual NAAQS finalized in section II above, characterizing localized air quality issues around local emission sources may become even more important. The EPA believes that adding a network design requirement to locate monitors in at-risk communities will improve our characterization of exposures for at-risk communities where localized air quality issues may contribute to air pollution exposures. Requiring that $PM_{2.5}$ monitoring stations be sited in at-risk communities will allow other methods to be operated alongside $PM_{2.5}$ measurements to support multiple monitoring objectives per 40 CFR part 58, appendix D, section 1.1. The EPA believes that it is appropriate to formalize the monitoring network's characterization of $PM_{2.5}$ concentrations in communities at increased risk to provide such areas with the level of protection intended with the $PM_{2.5}$ NAAQS. The addition of this requirement will also lead to enhanced local data that will allow air quality regulators help communities reduce exposures and inform future implementation and reviews of the NAAQS.

The EPA received comments concerning the proposed requirement to modify the $PM_{2.5}$ monitoring network design criteria to include an EJ factor that accounts for the proximity of populations at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern. Commenters included State, local, and Tribal air agencies and multijurisdictional organizations (MJOs) comprised of those agencies; industry and industry groups; other Federal, State, and local government entities; public health, medical, and environmental nongovernmental organizations (NGOs); and private citizens. The EPA proposed to require that sites located in at-risk communities (particularly those whose air quality is potentially affected by local sources of concern) should nonetheless meet the requirements to be considered representative of ''areawide'' air quality as this is consistent with all other minimally required sites. There were several other technical components of the proposed requirement for which we asked for comment, including: how to identify at-risk communities; the PM sources of concern important to consider; the datasets that can be used to identify communities with high exposures; the most useful measurement methods to collocate with $PM_{2.5}$ in at-risk communities; and the timeline to implement any new or moved sites.

Overall, most commenters were very supportive of the EPA's proposed modification to the $PM_{2.5}$ monitoring

[188] SES is a composite measure that includes metrics such as income, occupation, and education, and can play a role in populations' access to healthy environments and healthcare.

[189] Metropolitan and Micropolitan Statistical Areas are collectively referred to as ''Core-Based Statistical Areas.'' Metropolitan statistical areas have at least one urbanized area of 50,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. Micropolitan statistical areas are a set of statistical areas that have at least one urban cluster of at least 10,000 but less than 50,000 population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.

network design criteria to include an EJ factor that accounts for proximity of populations at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern. A few commenters offered detailed supporting comments. For example, one commenter recommended targeting investment in regulatory monitors in EJ communities, opining that there is presently a lack of equitable distribution of these monitors in low-income and minority communities. Another commenter supports the inclusion of an EJ factor in $PM_{2.5}$ monitoring network design criteria as a means to assess whether disparities in exposure are reduced in the future. The EPA appreciates the support for the proposed requirement and acknowledges the desirability of a goal to assess if disparities in exposure are reduced in the future as a result of these monitoring efforts.

Some commenters were generally supportive of the proposed requirement but suggested that the EPA should recast the approach in a more specific way or offered additional examples of sources of concern. For example, one commenter stated that $PM_{2.5}$ emissions from residential and commercial wood burning result in localized hotspots that are often not revealed by community air monitoring. Another commenter asked that the EPA adopt a strategy to monitor EJ communities near both larger well-known point sources of $PM_{2.5}$ and along traffic corridors as well as smaller sources that, when taken together, may create a large amount of emissions and health harms in the area. Another commenter stated that the national network of monitors operated by the EPA captures data used for generalized modeling, but overall monitoring is not as granular as one would expect, especially in urban areas. For instance, the commenter suggested that EPA could monitor suspected ''hot spots'' (*e.g.,* residential development adjacent to highways and active construction sites) to better manage and mitigate $PM_{2.5}$ pollution at their sites of origin, and that more extensive and granular monitoring data would also facilitate essential research and inform future evaluations and adjustments of the NAAQS. The EPA acknowledges these comments identifying other sources of concern, and we address these and other potential sources of concern below.

Among adverse comments, a few commenters stated that ''at-risk communities'' is not well defined. The EPA disagrees and directs those commenters to the numerous places where this definition is covered, including in Section II.B.2 of the proposal where we explained the term related to a variety of at-risk populations (88 FR 5591–92, January 27, 2023) as well as section 12.5 of the 2019 ISA (U.S. EPA, 2019a) and section 3.3.3 of the ISA Supplement (U.S. EPA, 2022a). Other commenters oppose the addition of the proposed monitoring because they feel it would reduce flexibility for agencies in deciding where they should site monitors, advocating that monitoring agencies should be afforded maximum flexibility to identify where to site monitors for at-risk areas. Because the EPA recognizes the challenges cited by these commenters related to establishing new ambient air monitoring stations, the EPA is finalizing the modified requirement on $PM_{2.5}$ monitoring network design criteria intended to address at-risk communities that allows flexibility regarding which EJ communities should be monitored. Finally, one commenter asked that the EPA clarify a specific metric to judge how to site monitors in at-risk communities. Instead, the EPA believes it is appropriate for agencies to recommend what they believe to be the most important things to consider for their sites to meet the $PM_{2.5}$ network design requirements and, thus, applying a new metric could take away from local priorities for at-risk communities.

A few commenters asked that the EPA require more monitoring than proposed. One commenter stated that it would be more beneficial to overburdened communities if air monitoring were required in all at-risk communities. A few commenters asked that EPA require additional monitoring for attainment of $PM_{2.5}$ NAAQS in EJ communities. In response to these comments, the EPA supports the SLT agencies' initiatives to conduct additional monitoring beyond the minimum monitoring requirements and network design criteria. In addition, the EPA supports agencies' use of alternative datasets such as sensors and sensors networks, satellites, and other non-regulatory monitoring where appropriate for non-regulatory data uses. The EPA notes that many monitoring agencies already operate more monitoring sites than are minimally required, and we expect this to continue as agencies consider siting monitors in at-risk communities.

However, the EPA also received substantial concerns from monitoring agencies about their resource constraints, including staffing to support any potential new monitoring. The EPA also notes that the existing and robust network of almost 1,000 $PM_{2.5}$ sites nationally is designed to continue to protect all populations at the level of the NAAQS discussed in section II of this final action by always having at least one site in the area of expected maximum concentration for each CBSA where monitoring is required. As a result of the revisions to the annual $PM_{2.5}$ NAAQS being finalized in this action, a small number of new monitoring sites will also be required under EPA's current minimum monitoring requirements. With the monitoring network design changes finalized in this rule, many of these existing and new sites will form an important sub-component of the $PM_{2.5}$ network by better characterizing air quality in at-risk communities, particularly with respect to sources of concern.

The EPA concludes that the requirements in this final rule for siting of monitoring in at-risk communities will meaningfully improve the $PM_{2.5}$ monitoring network and its characterization of air quality in at-risk communities, without placing substantial new resource burdens on States and their monitoring agencies that would be associated with requirements for additional monitoring sites. Therefore, the EPA is finalizing this part of the proposed action without requiring additional monitoring sites beyond what would be associated with the revised annual $PM_{2.5}$ NAAQS described in section II as they pertain to the minimum requirements associated with Table D–5 of Appendix D to Part 58—$PM_{2.5}$ Minimum Monitoring Requirements.

A few commenters asked that the EPA enhance monitoring in smaller cities and rural areas. One commenter asked for the EPA to extend the proposed monitoring network to Micropolitan Statistical Areas with populations of 10,000–50,000 and to rural areas. Another commenter pointed out that current air quality monitoring networks focus on urban and densely populated areas; therefore, rural areas are often not captured in this existing monitoring infrastructure, despite well-documented examples of high PM concentration in rural communities. The commenter believes this results in inadequate assessment of air pollution exposures for a substantial segment of the U.S. population. The EPA disagrees that there needs to be additional requirements for small CBSA's and rural areas. Regarding these comments, the EPA points out that we have a long-standing requirement for each State to monitor at background and transport sites (40 CFR part 58, appendix D, section 4.7.3—Requirement for $PM_{2.5}$ Background and Transport Sites). Also, if an agency deems it appropriate to do so, monitoring coverage of rural areas can be accomplished with other tools

such as sensors and sensors networks, satellites, and other non-regulatory monitoring. Although there may be short-term high exposures in rural areas, there is no evidence that long-term averages are higher in rural areas compared to urban areas with significantly higher density of populations and emissions. For smaller cities or rural areas that may have concentrations near the level of the $PM_{2.5}$ NAAQS finalized in section II above, monitoring agencies are encouraged to monitor and address emissions as appropriate.

Some commenters disagree that the proposed revision to the $PM_{2.5}$ monitoring network design criteria to address at-risk communities is needed. One commenter stated that including an EJ factor is not necessary because the current network is designed to protect all citizens. Another commenter stated that EJ factors could be cumbersome to implement. Another commenter asserted the proposal to add SLAMS in at-risk communities with higher $PM_{2.5}$ concentrations might create more granular data and provide for a greater margin of safety for those communities and monitors in such a way that data from those areas could misrepresent the larger area represented by the network. In response to the comment on the current network protecting all citizens, the EPA agrees that by measuring in the community with the highest concentration of $PM_{2.5}$ we protect other citizens; however, as stated in the proposal, the EPA believes that adding a requirement for sites with an EJ factor near sources of concern will enhance the overall network to the benefit of all citizens. Also, we anticipate that with the more protective annual NAAQS finalized in section II above, characterizing localized air quality issues will become even more important around local emission sources. As for EJ factors being cumbersome to implement, the EPA disagrees because there are many such locations already operating successfully in the current network. Regarding the comment that sites in at-risk communities may misrepresent the larger area represented by a particular network, the EPA notes that pursuant to 40 CFR part 58, minimally required sites in a given network are to represent area-wide air quality; therefore, sites in at-risk communities, by definition, would be representative of the communities within the network in which they are sited for the level of protection intended under the annual $PM_{2.5}$ NAAQS.

In the proposal, the EPA identified that, in light of the evidence of increased risk to at-risk communities, it would be appropriate to better characterize exposures for communities in proximity to local sources of concern (88 FR 5673–76, January 27, 2023). Thus, the EPA proposed that enhanced networks should include representation of at-risk communities living near emission sources of concern (*e.g.,* major ports, rail yards, airports, industrial areas, or major transportation corridors). The EPA requested comment on the types of sources of concern most important to consider. In addition to supporting the types of sources the EPA identified in the proposal, commenters also identified several additional localized sources such as railroads, stationary sources, transportation facilities, and communities with high numbers of wood stoves.

A few commenters suggested the inclusion of sources that are often considered line and/or area sources, *e.g.,* traffic corridors and emissions from federally regulated facilities, military installations, and national forests. Commenters also identified other sources usually associated with long-range transport such as smoke from wildfire and prescribed fires and long-distance transport of PM, for example from Saharan dust and other international transport. As explained in the proposal, the site with the highest expected $PM_{2.5}$ is already required to have a monitor by our long-standing requirement that monitors be placed ''. . . in the area of expected maximum concentration'' (§ 58.1 and appendix D, section 4.7.1(b)(1)). The EPA expects that both sites with the expected maximum concentration and sites specifically placed in at-risk communities would be impacted by any long-range transport in the area. Therefore, the EPA believes any emphasis on the sources of concern should prioritize localized sources, including point, area, and line sources of concern impacting the at-risk community of interest. Therefore, based upon the comments, the EPA is finalizing a broader example list of sources of concern to include localized sources such as point sources and transportation facilities, since these are the most commonly expected additional sources of concern. In response to the other sources of concern suggested by commenters, the EPA notes that while it has provided examples, the siting of monitors in EJ communities would not be limited to these examples. Thus, the revised set of examples would include ''a major industrial area, point source(s), port, rail yard, airport, or other transportation facility or corridor.'' In finalizing this modified list of examples, the EPA is not looking to prioritize one type of source category over another; rather, we intend to further illustrate the types of localized sources of pollution that might impact at-risk communities such that the siting of monitors nearby may be appropriate.

One commenter noted that the proposal may have unintentionally taken out the requirement related to specific design criteria for $PM_{2.5}$ in 40 CFR part 58, appendix D, 4.7.1(b)(3) that, for an area with a requirement for an additional SLAMS monitor, it should ''be sited in an area of poor air quality.'' Thus, the language as proposed neither requires that such monitors be sited in areas of poor air quality, nor does it require that the monitor be sited in an area that is anticipated to experience poor air quality from unspecified (and thus potentially relatively insignificant) sources in the area. The EPA agrees that this was not our intention; the EPA wants to protect populations in at-risk communities by ensuring they are protected by the NAAQS when there are sources of concern that may be impacting them (*i.e.,* not insignificant sources). Thus, the EPA is reinstating this requirement in the network design language and combining it with the examples of the types of localized sources of concern: ''For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community with poor air quality, particularly where there are anticipated effects from sources in the area (*e.g.,* a major industrial area, point source(s), port, rail yard, airport, or other transportation facility or corridor).''

To ensure minimally required monitoring sites appropriately represent exposures in at-risk communities, the EPA proposed that sites represent ''area-wide'' air quality near local sources of concern (88 FR 5674, January 27, 2023). Sites representing ''area-wide'' air quality are those monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are identified as being representative of many such locations in the same Metropolitan Statistical Area (MSA).[190] Most existing—as well as new or moved sites—are expected to be neighborhood-scale, which means that the monitoring stations would typically represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers per part 58, appendix D, section 4.7.1(c)(3). Additionally, as described in § 58.30,

[190] MSA means a CBSA associated with at least one urbanized area of 50,000 population or greater. The central-county, plus adjacent counties with a high degree of integration, comprise the area.

sites representing ''area-wide'' air quality have a long-standing applicability to both the annual and 24-hour $PM_{2.5}$ NAAQS. Our proposed requirement for siting monitors in communities representing ''area-wide'' air quality is consistent with other network design objectives pursuant to which we seek to have monitors located where people live, work, and play.

The EPA received a few comments on its proposed requirement that minimally required sites represent ''area-wide'' air quality. One commenter stated that the inclusion of a provision for EJ would narrow the location of monitors to certain communities that may not best represent ''areawide'' air quality. Another commenter asked the EPA to consider removing requirements that sites be area-wide, since 24-hour and annual averaging times would miss short, elevated pollution events. A couple commenters had concerns with the difference in the scale of representation between EJ monitors using small scale and other NAAQS monitors using area-wide scale, in that area-wide scale would not protect those most at risk. However, another commenter agreed with the EPA that sites representing at-risk communities should represent area-wide air quality. In addition to these comments, the EPA received many comments with support for its proposed modifications to the network design criteria as whole.

Regarding whether narrowing the location to certain communities may not best represent ''area-wide'' air quality, the EPA notes that sites are either identified as being area-wide or not; the EPA did not suggest it was seeking a best ''area-wide'' location. In response to the comment that area-wide site may miss short, elevated pollution events, the EPA is aware that there can be local, short-term spikes in $PM_{2.5}$ concentrations. However, the network design criteria associated with minimally required sites is applicable to both the annual and 24-hour $PM_{2.5}$ NAAQS, and the EPA believes it is appropriate to continue to ensure all minimally required sites have the most utility and remain applicable to both forms of the $PM_{2.5}$ NAAQS. The identification of unique micro- and middle-scale sites was directed at discretionary efforts of any monitoring agency, with the recognition that such sites, (*i.e.,* relatively unique micro-scale, or localized hot spot, or unique middle-scale impact sites), are not applicable to the annual NAAQS as described in § 58.30—Special consideration for data comparison to the NAAQS.

After considering all the comments on this topic, the EPA is finalizing this part of the modification to the network design criteria to maintain, consistent with our long-standing network design criteria, that all minimally required sites are to represent area-wide air quality.

In addition to using data from the robust network of almost 1,000 $PM_{2.5}$ sites for NAAQS and AQI purposes, having a stable network of long-term sites is especially valuable to examine trends and to inform long-term health and epidemiology studies that support reviews of the PM NAAQS. Therefore, while we proposed to add a $PM_{2.5}$ network design criterion to address at-risk communities, many sites are likely already in valuable locations meeting one of the existing network design criteria (*i.e.,* being in an area-wide area of expected maximum concentration or collocated with near-road sites) and supporting multiple monitoring objectives. Also, in many communities, there may already be sites meeting the network design criterion we proposed for at-risk communities. Thus, acknowledging the value of having long-term data from a consistent set of network sites, the EPA believes that moving sites should be minimized, especially in MSAs with a small number of sites. However, because a small number of new sites are expected to be required due to the existing minimum monitoring requirements (40 CFR part 58, appendix D, Table D–5) [191] and the revised primary annual $PM_{2.5}$ NAAQS detailed in section II, and because sites occasionally have to be moved—due to, for example, loss of access to a site or a site no longer meeting siting criteria—the EPA believes it is appropriate to prioritize establishing sites in at-risk communities near sources of concern, whenever new sites are established, whether because it is a new site or a replacement for a prior site that must be moved. The EPA accordingly proposed that annual monitoring network plans (40 CFR 58.10(a)(1)) and 5-year assessments (40 CFR 58.10(d)) that include any of the few new sites that will be required include a commitment to examine the ability of existing and proposed sites to support air quality characterization for areas with at-risk populations in the community and the objective discussed herein.

In the proposal, the EPA identified that assessing and prioritizing at-risk communities for monitoring can be accomplished through several approaches (88 FR 5675). The most critical aspect of prioritizing which communities to monitor is their representation of the at-risk populations described earlier in this section. The other major consideration is whether the community is near a source or sources of concern. While many CBSAs have one or more sources of concern described above, some CBSAs will not have a quantity of emissions from sources of concern that result in an elevated level of measured $PM_{2.5}$ concentrations in surrounding communities. The siting criteria to be ''in the area of expected maximum concentration,'' § 58.1 & appendix D, section 4.7.1(b)(1) ensures there is a monitoring site in the community with the highest exposure in each CBSA with a monitoring requirement. Some CBSAs may also have a requirement to collocate a $PM_{2.5}$ monitor at a near-road NO_2 station. Therefore, the EPA believes that for cases where an additional $PM_{2.5}$ site is required, we should include a criterion that the site be in an at-risk community when there are no sources of concern identified in that CBSA, or such sources do exist but are not expected to lead to elevated levels of measured $PM_{2.5}$ concentrations.

In its proposal, the EPA highlighted that tools such as the EPA's EJSCREEN [192] are available to identify the at-risk communities intended for monitoring as part of the proposed revision to the $PM_{2.5}$ network design criteria (88 FR 5675–76, January 27, 2023). The EPA solicited comment on other tools and/or datasets that can be utilized to identify at-risk communities. In addition to support for using EJSCREEN, commenters identified several other options to identify at-risk communities intended for monitoring as part of the proposed revision to the $PM_{2.5}$ network design criteria. Among similar tools, one commentor suggesting using CalEnviroScreen.[193] Commenters also identified different options for models including InMAP,[194] satellite-derived models that can be employed to help identify EJ communities, and hybrid models. A few commenters also suggested using sensors and sensor networks such as the BlueSky [195] and PurpleAir [196] sensors.

The EPA supports the use of other State and local tools designed to help identify the at-risk communities that

[191] Gantt, B. (2022). Analyses of Minimally Required $PM_{2.5}$ Sites Under Alternative NAAQS. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

[192] See: *https://www.epa.gov/ejscreen.*

[193] See: *https://oehha.ca.gov/calenviroscreen.*

[194] See: *https://inmap.run/#home.*

[195] Mention of commercial names does not constitute EPA endorsement.

[196] Mention of commercial names does not constitute EPA endorsement.

should be monitored to meet the revised network design criteria. The EPA additionally agrees with commenters that the use of models as well as sensors and sensor networks may be appropriate and helpful in identifying the most appropriate at-risk communities in which to locate monitors.

For at-risk communities, monitoring agencies need data that can best inform where there may be elevated levels of exposures from sources of concern. While we use FRMs and FEMs to determine compliance with the NAAQS, data from these methods will only be available at existing sites. However, there are several additional datasets available that may be useful in evaluating the potential for elevated levels of exposure to communities near sources of concern. In the proposal, EPA identified potential non-regulatory monitoring datasets such as CSN, IMPROVE, and AQI non-regulatory $PM_{2.5}$ continuous monitors; modeling data that utilizes emission inventory and meteorological data; emerging sensor networks such as those that comprise EPA and the USFS's Fire and Smoke Map; [197] and satellites that measure radiance and, with computational algorithms, can be used to estimate $PM_{2.5}$ from aerosol optical depth (AOD) (88 FR 5675–76, January 27, 2023). The EPA solicited comment on datasets most useful to identify communities with high exposures for $PM_{2.5}$ NAAQS (*i.e.,* annual or 24-hour). In addition to providing information about datasets that can inform the NAAQS comparison, commenters additionally identified several types of datasets that may be useful to identify where there may be elevated levels of exposures from sources of concern. These datasets include satellite measurements, sensors, and sensor network data, which may all be useful to find hot spots in communities. Commenters also identified EJScreen and CalEnviroScreen, which are screening and mapping tools that utilize several datasets. Another commenter stated that to better understand exposure differences in disadvantaged communities, shorter measurement intervals should be measured and reported.

In considering the datasets identified in the proposal as well as the ones commenters provided, the EPA believes all the datasets have value to help inform where there may be elevated levels of exposures from sources of concern. However, each of them may also have limitations and, therefore, users should be careful not to rely solely on one dataset versus another for all purposes. Fortunately, many of the available datasets are becoming easier to work with and more accessible, which will allow interested parties and monitoring agencies the opportunity to efficiently review the datasets and determine best applicability. For all of these reasons, the EPA is not finalizing a requirement to use a specific dataset or tool to identify at risk communities; however, whatever datasets a monitoring agency elects to use, its plan to use such data for purposes of meeting the network design requirements will be subject to EPA approval as part of the 40 CFR 58.10 annual monitoring network plan. Regarding the comment recommending shorter measurement intervals in measuring and reporting data to better understand exposure differences in disadvantaged communities, the EPA agrees and generally supports use of continuous methods. While we generally support use of continuous methods, approved filter-based technologies and methods also provide valuable air quality information. Therefore, the EPA is not requiring the use of automated continuous methods beyond what is already required in 40 CFR part 58, appendix D, section 4.7.2—Requirement for Continuous $PM_{2.5}$ Monitoring.

The monitoring methods appropriate for use at required $PM_{2.5}$ sites in at-risk communities are FRMs and automated continuous FEMs (88 FR 5675–76, January 27, 2023). These are the methods eligible to compare to the $PM_{2.5}$ NAAQS, which is the primary objective for collecting this data. There are several other monitoring objectives that would benefit from the use of automated continuous FEMs. For example, having hourly data available from automated continuous FEMs would allow sites to provide data in near-real time to support forecasting and near real-time reporting of the AQI. Automated continuous methods are also useful to support evaluation of other methods such as low-cost sensors. When used in combination with on-site wind speed and wind direction measurements, automated FEMs can provide useful pollution roses, which help in identifying the origin of emissions that affect a community. Additionally, when collocated with continuous carbon methods such as an aethalometer, automated FEMs can help identify potential local carbon sources contributing to increased exposure in the community. While either FRMs or automated FEMs may be used at a site for comparison to the $PM_{2.5}$ NAAQS, the EPA supports use of automated continuous FEMs at sites in at-risk communities.

The EPA requested comment on the measurement methods most useful to collocate with $PM_{2.5}$ in at-risk communities (88 FR 5675–76, January 27, 2023), and a few commenters provided input. One commenter recommended that the EPA should employ supplemental technologies and systems to increase coverage of the regulatory monitoring network and obtain more complete data to further protect public health and address environmental injustice in air pollution exposure. Another commenter recommended that the EPA invest in community-led monitoring and mobile air quality monitoring with a goal of recording block-level variabilities in data. And another commenter cited the value of community-deployed $PM_{2.5}$ monitoring.

The EPA appreciates the comments provided on the measurement methods most useful to collocate with $PM_{2.5}$ monitoring sites in at-risk communities. Because the use of methods beyond the required $PM_{2.5}$ FRMs or FEMs or other criteria pollutant measurements meeting a NAAQS monitoring requirement is voluntary, the establishment of $PM_{2.5}$ NAAQS comparable sites in at-risk communities will allow for collaboration at multiple levels. The EPA strongly encourages such collaboration with impacted communities, and the measurement methods discussed here should be considered for use as appropriate.

In the proposal, the EPA identified that, to meet the revised network design criteria, there will be only a few new sites required,[198] plus any potentially moved sites in cases where an existing site lease is lost or otherwise requires relocation (88 FR 5675–76, January 27, 2023). To handle these new or relocated sites, the EPA proposed to build upon our existing regulatory process for selecting and approving these sites under 40 CFR 58.10 (88 FR 5676, January 27, 2023). In the proposal, we stated it would be appropriate to provide at least 12 months from the effective date of the final rule to allow monitoring agencies to initiate planning to implement these measures by seeking input from communities and other interested parties and considering whether to revise their $PM_{2.5}$ networks

[197] See: *https://fire.airnow.gov/.*

[198] Gantt, B. (2022). Analyses of Minimally Required $PM_{2.5}$ Sites Under Alternative NAAQS. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.*

or explain how their existing networks meet the objectives of the proposed modification to the network design criteria. Thus, the EPA proposed that monitoring agencies should address their approach to the question of whether any new or moved sites are needed and identify the potential communities in which the agencies are considering adding monitoring, if applicable, as well as identifying how they intend to meet the revised criteria for $PM_{2.5}$ network design to address at-risk communities in the agencies' annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2024 (see 40 CFR 58.10). Specifics on the resulting new or moved sites for $PM_{2.5}$ network design to address at-risk communities were proposed to be detailed in the annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2025 (40 CFR 58.10). The EPA proposed that any new or moved sites would be required to be implemented and fully operational no later than 24 months from the date of approval of a plan or January 1, 2027, whichever comes first, but the EPA solicited comment on whether less time is needed (*e.g.,* 12 months from plan approval and/or January 1, 2026).

The EPA received a few comments on its proposed timeline for monitoring agencies to identify, propose, and ultimately bring any new or moved sites online. One commenter asked that the timeline give states more time to start or move sites. A few commenters asked that the EPA only require meeting a timeline for identifying whether any new or moved sites are needed after the EPA has provided the monitoring agencies with guidance on the priority of the potential at-risk communities. One of those commenters further requests that the EPA allow at least 24 months from the date of approval of a § 58.10 monitoring plan identifying any relocation of monitoring sites or establishment of new monitoring sites to implement any changes to the network, citing the need for more time to work with local officials, procure monitoring equipment, and contract for services, all of which can cause significant delays in establishing a monitoring site. Another commenter asked that the EPA remain attentive to the challenges that States, and air agencies face regarding recruiting and retaining the specialized staff needed to support their existing regulatory monitoring networks and the capital resources needed to implement and sustain new monitoring stations in areas that are clearly meeting the existing PM NAAQS or any revised PM NAAQS. Another commenter stated that the July 1, 2024, timeline for a network evaluation this complex is insufficient, noting that they submit their draft annual monitoring network plan for public review and comment in mid-April for 30 days. Because the final plan is due July 1 and must include all comments and responses and describe any changes based on those comments, the timeline does not take these requirements into consideration by allowing for the more extensive assessment of changes that may be needed to meet the proposed new monitoring requirements. The commenter stated that it would be appropriate to provide at least 12 months from the effective date of this final rule for monitoring agencies to initiate planning to implement these measures, seek input, consider revisions to their $PM_{2.5}$ networks, and explain how their existing networks meets the objectives of the final rule. The commenter notes that that SLT agencies should be provided a minimum of 18 months after the final recommendation is published to add this information to their § 58.10 annual monitoring network plans. Another commenter encourages the EPA to retain the proposed deadline for any newly required monitoring stations in at-risk communities to be operational (*i.e.,* 24 months after the July 2025 network plan approval or January 1, 2027, whichever is earlier). While the need for this data is urgent, the commenter stated that the process for procuring instrumentation, securing leases, and building permits, and other logistics in constructing new monitoring sites can take a significant amount of time, some of which are outside of agencies' control.

As stated earlier, the EPA received strong support for our proposal to modify the $PM_{2.5}$ monitoring network design criteria to include an EJ factor that accounts for proximity of populations at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern from a wide range of commenters. A few commenters support the timeline proposed, a few others support starting any new or moved sites sooner than proposed, while other commenters asked for more time or offered conditions regarding how to establish an appropriate timeline.

The EPA disagrees with the commenter that suggested the EPA should only require agencies to meet a timeline to identify whether any new or moved sites are needed after the EPA has provided the monitoring agencies with guidance on the priority of the potential at-risk communities, because the regulatory text provides all the guidance required for agencies to begin this process. As we explained above, the EPA does not anticipate that many new or moved sites will be required based on the final rule because we think most sites are already in suitable locations and long-term sites are highly valued. Also, monitoring agencies have discretion to provide to the EPA their recommendations regarding how they intend to meet the modifications to the $PM_{2.5}$ monitoring network design criteria to include an EJ factor that accounts for proximity of populations at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern. Overall, the EPA believes that having sites in the areas of expected maximum concentrations will best ensure that all communities are protected. Since there may be multiple choices for sites in EJ areas near sources of concern, the EPA acknowledges that there may be many locations that can meet the revised $PM_{2.5}$ network design criteria. While, as we explained earlier, we want such sites to also be in areas of poor air quality, the sites in the area of maximum concentration will ensure that all communities are protected, there can be more flexibility afforded in the selection amongst at-risk communities to meet the revised requirements, since any alternative at-risk communities would already be protected.

The EPA considered both the concerns and support for the timeline proposed and clarifies that the component of the proposed requirement regarding the need to identify potential new sites or an intention to move sites to be included in the annual monitoring network plan due to EPA on July 1, 2024, would be satisfied with a statement of intent to pursue a new site per the revised network design criteria and in consideration of the minimum monitoring requirements. While monitoring agencies may provide as much detail as they deem appropriate regarding the revised $PM_{2.5}$ network design criteria in their annual monitoring network plans due on July 1, 2024, there is no expectation that any details on site-specific information would be included at that stage. We encourage agencies to provide their initial thinking on the communities they are most interested in monitoring pursuant to the revised network design criteria. Therefore, the EPA is finalizing the timeline as proposed, including the provision that monitoring agencies report their intention to add or move sites, where required, in their annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2024 (40 CFR 58.10). The

monitoring agencies will then provide specifics on any new or moved sites for $PM_{2.5}$ network design to address at-risk communities in the annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2025 (40 CFR 58.10). And any new or moved sites shall be implemented and fully operational no later than 24 months from the date of approval of a § 58.10 plan, or January 1, 2027, whichever comes first.

In summary, the EPA is finalizing modifications to the $PM_{2.5}$ network design criteria to include an EJ factor to address at-risk communities with a focus on exposures from sources of concern in areas of poor air quality. While this modification to the $PM_{2.5}$ network design requires sites to be located in at-risk communities, particularly those whose air quality is potentially affected by local sources of concern, such sites must still meet the requirement for being considered ''area-wide'' air quality. In finalizing this modification to the $PM_{2.5}$ network design requirement, the EPA is making two changes in the final rule response to the comments received. First, the EPA is broadening our examples of ''sources of concern'' to include localized sources such as point sources and major transportation facilities or corridors. Second, the EPA is reinstating ''poor air quality'' in our requirement for the modified network design criteria, meaning the revised $PM_{2.5}$ network design requirement now states: ''For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community with poor air quality, particularly where there are anticipated effects from sources in the area (*e.g.,* a major industrial area, point source(s), port, rail yard, airport, or other transportation facility or corridor).'' All other aspects of the $PM_{2.5}$ network design requirements are being finalized as proposed.

5. Revisions to Probe and Monitoring Path Siting Criteria

The EPA proposed changes to monitoring requirements in the Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring (88 FR 5676–78, January 27, 2023). Since 2006, the EPA finalized multiple rule revisions to establish siting requirements for $PM_{10–2.5}$ and O_3 monitoring sites (71 FR 2748, January 17, 2006), Near-Road NO_2 monitoring sites (75 FR 6535, February 9, 2010), Near-Road CO monitoring sites (76 FR 54342, August 31, 2011), and Near-Road $PM_{2.5}$ monitoring sites (78 FR 3285, January 15, 2013). Through these previous revisions to the regulatory text, some requirements were inadvertently omitted, and, over time, the clarity of this appendix was reduced through those omissions that, in a few instances, led to unintended and conflicting regulatory requirements. The EPA proposed to reinstate portions of previous Probe and Monitoring Path Siting Criteria Requirements from previous rulemakings, where appropriate, to restore the original intent.

The EPA only received a few comments on the proposed rulemaking pertaining to the proposed changes regarding probe and monitoring path siting criteria for ambient air quality monitoring, most of which were supportive of the proposed revisions. One commenter noted that the image for Figure E–1 in Appendix E to part 58 was distorted and of extremely poor quality, rendering the text in places almost unreadable (88 FR 5712, January 27, 2023). The EPA makes several references to Figure E–1, which provides detailed information needed for assessing a range of acceptable probe distances from roadways based on a monitor's spatial scale. The commenter also stated that a higher quality image is needed for the figure so that agencies can fully interpret the figure to the extent that EPA requires. The EPA agrees with the commenter that a higher quality image for Figure E–1 is important and needed. Based on this comment, the EPA is finalizing the revision to Figure E–1 to clearly communicate the requirements of appendix E.

The EPA is revising appendix E in its entirety as proposed (88 FR 5709–5717, January 27, 2023) for clarity and as described in detail below.

a. Separate Section for Open Path Monitoring Requirements

The EPA proposed to relocate all open path monitor siting criteria requirements to a separate section in appendix E from those requirements for siting samplers and monitors that utilize probe inlets (88 FR 5676, January 27, 2023). Separate sections for these distinct monitoring method types allows the EPA to more clearly articulate minimum technical siting requirements for each.

The EPA received one supportive comment to adopt this change and received no adverse comments. Another commenter stated the regulatory text of the proposal improves the clarity of the appendix but encouraged the EPA to break the summary tables down further into more manageable components (perhaps by pollutant). The commenter stated that summary tables for the proposed appendix continue to be a ''jumbled mess of regulatory requirements.'' The EPA agrees that the summary tables E–3 and E–6 in the proposal could be improved further. Also, the EPA found that footnote 3 of Table E–6 in the proposed rule was incomplete and corrected this editorial error.

Therefore, the EPA is making editorial changes to both summary tables E–3 and E–6 and finalizing the remainder of the language as proposed with the open path monitor siting criteria requirements placed into a separate section of the appendix.

b. Distance Precision for Spacing Offsets

The EPA proposed to require that when rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures (88 FR 5676, January 27, 2023). The EPA proposed to communicate this rounding requirement in the regulatory text using footnotes in the tables of this appendix.

The EPA received two supportive comments and no adverse comments regarding this proposed change. While supportive of the proposal, one of the two supporting comments suggested it would be clearer if EPA explicitly defined a decimal in the distance values and round to the nearest tenths place for these assessments. The EPA disagrees with this recommendation because in some cases it would be more restrictive and burdensome than the proposed requirement that was intended to provide both clarity and flexibility. Therefore, the EPA is finalizing the language as proposed.

c. Summary Table of Probe Siting Criteria

The EPA proposed to provide additional specificity and flexibility to the summary table for probe siting criteria by changing the ''>'' (greater than) symbols to ''≥'' (greater than or equal to) symbols in the summary table E–4 (88 FR 5676, January 27, 2023). Because one commenter pointed out to the EPA that in the prior version of the rule there was no table E–4, as a clerical matter, we have renumbered this summary table to table E–3 in the final rule. This proposed minor revision to the summary table more clearly expresses the EPA's intent that the distance offsets provided in the summary tables in appendix E are acceptable for NAAQS compliance monitoring.

The EPA received one comment supporting the proposal. The EPA received no adverse comments. Because

one commenter pointed out to the EPA that in the prior version of the rule there was no table E–4, as a clerical matter, we have renumbered this summary table to table E–3 in the final rule. Therefore, the EPA is updating the table numbering and otherwise finalizing the tables as proposed.

d. Spacing From Minor Sources

The EPA proposed to clarify and provide flexibility regarding siting monitors near minor sources by changing a requirement to a goal (88 FR 5676–77, January 27, 2023). To accomplish this, the EPA proposed to replace the ''must'' in the regulation with a ''should.'' While the EPA proposed to change this requirement to a goal, the EPA reiterated in the proposal that it recommends that sites with minor sources be avoided whenever practicable and probe inlets should be spaced as far from minor sources as possible when alternative monitoring stations are not suitable.

The EPA received one comment supporting the proposed revision and received no adverse comments. Therefore, the EPA is finalizing the language as proposed.

e. Spacing From Obstructions and Trees

The EPA proposed to clarify and redefine that the minimum arc required to be free of obstructions for a probe inlet or monitoring path is 270-degrees and that probe inlets must be no closer than 10-meters to the driplines of any trees (88 FR 5677, January 27, 2023). These changes were proposed because of inconsistencies introduced into the rule with the 2006 rulemaking. Both are discussed in more detail in the following sections.

The majority of comments received were supportive of these proposed siting amendments and clarifications. Two commenters were not supportive of this proposal. One adverse comment focused on the potential that site modifications would be required if the minimum arc required to be free of obstructions for a probe inlet is 270-degrees. The second adverse comment pertained to the proposal to clarify distance requirements from tree driplines. The commenter stated they would expect significant challenges in meeting the proposed 20-meter tree dripline distance. This comment is not a substantive negative comment because the 20-meter distance provided in the proposal is a goal and not a requirement. As such, monitoring organizations should not expect additional challenges in meeting the probe siting requirements. One supportive commenter on the 270-degree minimum arc proposal also requested that the EPA acknowledge that some cases exist where monitoring is desired or necessary to protect the public health, but siting criteria cannot be met.

Based on the only two negative comments received from monitoring agencies or organizations, one of which was not substantive, the EPA believes most sites already meet these proposed requirements related to the arc and distance from dripline. However, the EPA also acknowledges that there may be limited cases where this proposed revision may require site modifications, and some sites may not be able to be achieve the proposed siting requirements, even with modifications to the site. For cases where long-term trend sites or monitors that determine the design value for their area cannot reasonably meet these regulatory siting requirements, the EPA encourages monitoring organizations to work with their respective EPA Regional offices to determine if a waiver from this siting criteria would be appropriate under appendix E, section 10.

These siting requirements are discussed in more detail below in sections VII.B.5.f and VII.B.5.h.

f. Reinstating Minimum 270-Degree Arc and Clarified 180-Degree Arc

The EPA proposed to correct identified inconsistencies in the 270-degree requirement for unrestricted airflow to the probe inlet by reinstating the requirement stated in appendix E, paragraph 4(b), and to clarify that the continuous 180-degree minimum arc of unrestricted airflow provision is reserved for monitors sited on the side of a building or wall to comply with network design criteria requirements specified in appendix D of part 58 (88 FR 5677, January 27, 2023).

The EPA received two comments regarding this proposal, with one being supportive and one being negative. The adverse comment focused on the potential that site modifications would be required if this revision was made. The commenter supporting the proposal also requested that the EPA acknowledge that some cases exist where monitoring is desired or necessary to protect the public health, but siting criteria cannot be met. The EPA agrees with both commenters and acknowledges that there does exist limited cases where this proposal would require site modifications and some sites may not be able to be achieve the proposed siting requirement even with modifications to the site. For these cases, and especially when long-term trend sites or monitors that determine the design value for their area cannot reasonably meet these regulatory siting requirements, the EPA encourages monitoring organizations to work with their respective EPA Regional Offices to determine if a waiver from this siting criteria is appropriate through the provisions found in Section 10 of this appendix.

Based on the EPA only receiving a single negative comment regard the 270-degree and 180-degree provisions the EPA thinks most sites already meet these proposed requirements. Additionally, as stated above, the EPA is also retaining waiver provisions from these siting requirements for the remaining cases that can be exercised when appropriate. Therefore, the EPA is finalizing the language as proposed.

g. Obstacles That Act as Obstructions

The EPA proposed to clarify the definitions of ''obstructions'' and ''obstacles'' in the regulatory text (88 FR 5677, January 27, 2023). Stating that, ''[o]bstructions to the air flow of the probe inlet are those obstacles that are horizontally closer than twice the vertical distance the obstacle protrudes above the probe inlet and can be reasonably thought to scavenge reactive gases or to restrict the airflow for any pollutant,'' the EPA proposed to reiterate that the EPA does not generally consider objects or obstacles such as flag poles or site towers used for NO_y convertors and meteorological sensors, etc., to be deemed obstructions.

The EPA received one comment supporting the proposal and received no adverse comments. Therefore, the EPA is finalizing the definitions as proposed.

h. 10-Meter Tree Dripline Requirement

The EPA proposed to reconcile the conflicting requirements in 5(a) and the prior table E–4 footnote 3 by clarifying that the probe inlet must always be no closer than 10 meters to the tree dripline (88 FR 5677, January 27, 2023). The EPA also proposed to reinstate the goal ''that monitor probe inlets should be at least 20-meters from the driplines of trees,'' a goal that was inadvertently omitted during previous rule revisions. In addition, the EPA proposed to clarify that if a tree or group of trees is considered an ''obstruction,'' section 4(a) will apply.

As described above, the majority of comments received were supportive of the EPA proposed amendments and clarification, with two commenters focused on the possibility that monitoring agencies may not be able to meet the revised siting requirements. Specific to the proposed dripline requirement, the EPA reiterates that the

20-meter tree dripline offset is not a requirement, but rather a goal. Monitoring programs should as much as practicable attempt to meet this 20-meter tree dripline offset goal but are only required to be at least 10 meters removed from tree driplines. If these requirements cannot be met, the EPA encourages monitoring organizations to contact their respective EPA Regional offices to determine if a waiver from this siting criteria would be appropriate under appendix E, section 10.

Another commenter recommended that the proposal should also include an elevation specification. For instance, if a monitor is on the roof of a shelter, a tree below that roof should not be considered an obstruction no matter the distance to the dripline. The EPA considers this scenario to occur in practice only rarely. The EPA agrees that when the overall tree height is less than the height of the probe inlet, the tree is not obstructing the airflow to the probe inlet. However, a tree in such proximity to the probe inlet in many cases is not likely to remain at a height lower than the probe inlet. The EPA considers a scenario such as this to be best addressed in the waiver provisions of this appendix due both to the rarity of this occurring as well as the need for the EPA to periodically reassess whether tree growth has adversely impacted the site conditions.

For these reasons, the EPA is finalizing the language as proposed.

i. Spacing Requirement for Microscale Monitoring

The EPA proposed to require that microscale sites for any pollutant shall have no trees or shrubs blocking the line-of-sight fetch between the monitor's probe inlet and the source under investigation (88 FR 5677, January 27, 2023). This proposed revision would bring consistency between near-road monitoring stations and other microscale monitoring.

The EPA received one comment on this proposed requirement expressing concerns regarding its practicality and legality. The commenter stated agencies may at times want to site a monitor close to a source, but the closest location will have trees in the line of sight on private property. Additionally, in some cases, the trees may have been planted for the purpose of reducing off-property emissions from a source such as a Concentrated Animal Feeding Operation (CAFO). The commenter further stated that the proposal mandates that State agencies order the removal of trees from private property to collect valid data.

The EPA disagrees that the proposed requirement is impractical or unlawful. The proposed requirement would not require, mandate, or otherwise empower monitoring agencies to force the removal of trees on private property. The EPA agrees with the commenter that trees may at times be planted as part of control strategies to reduce offsite emissions and thus protect the public, but the EPA disagrees with the commenter that the trees must be removed to perform ambient air monitoring in these locations. Rather, if trees or shrubs block the line-of-sight fetch between the monitor's probe inlet and the source under investigation, it is the EPA's position that, for most cases, a microscale designation does not accurately reflect the monitoring scale for this location, and instead the EPA would recommend that the monitoring scale be designated to a more representative monitoring scale such as middle scale or neighborhood scale.

Moreover, for cases where long-term trend sites or monitors that determine the design value for an area cannot reasonably meet this regulatory siting requirement, the EPA encourages monitoring organizations to work with their respective EPA Regional offices to determine if a waiver from this siting criteria may be appropriate under appendix E, section 10.

For these reasons, the EPA is finalizing the language as proposed.

j. Waiver Provisions

The EPA proposed to maintain the appendix E, section 10 waiver provisions in the current regulation for siting criteria, but to modify section 10.3 to require that waivers from the probe-siting criteria must be reevaluated and renewed minimally every 5 years (88 FR 5677–78, January 27, 2023).

The EPA received one comment supporting the proposal and no adverse comments. Therefore, the EPA is finalizing the language as proposed.

k. Acceptable Probe Materials

The EPA proposed to expand the list of acceptable probe materials for sampling reactive gases in appendix E, section 9, from just borosilicate glass and fluorinated ethylene propylene (FEP) Teflon®, or their equivalents. The EPA proposed to add polyvinylidene fluoride (PVDF), also known as Kynar®, polytetrafluoroethylene (PTFE), and perfluoroalkoxy (PFA) to the list of approved materials for efficiently transporting gaseous criteria pollutants, and the use of Nafion™ upstream of ozone analyzers (88 FR 5678, January 27, 2023). Mention of trade names or commercial products does not constitute endorsement.

The EPA received two comments supporting the proposal and received no adverse comments. Therefore, the EPA is finalizing the language as proposed.

D. Incorporating Data From Next Generation Technologies

In the proposal, the EPA requested comment on how to incorporate data from next generation technologies into Agency efforts (88 FR 5678–80, January 27, 2023). The near real-time integration of data from $PM_{2.5}$ continuous monitors, sensors, and satellites has allowed the EPA to use data in certain informational applications such as EPA and USFS's Fire and Smoke Map.[199] This mapping product uses Application Program Interfaces (APIs) where data sets are automatically shared on prespecified computer servers. Given the success of the Fire and Smoke Map, the EPA indicated interest in exploring the use of next-generation technologies to develop additional approaches, products, and applications to help address important non-regulatory air quality data needs. Therefore, the EPA solicited comment on the most important data uses and data sets to consider in such future initiatives. Such approaches and/or products could utilize historical or near real-time data. The EPA sought this input and prioritization on use of next generation technologies to help improve the utility of data to better support air quality management to improve public health and the environment.

The EPA received comments from about two dozen entities on its request for comments on how to incorporate data from next generation technologies. The entities that provided comment included federal agencies; representatives of industry and industry groups; public health, medical, and environmental organizations; State, local and related multi-state organizations involved in air program management; Tribes and Tribal organizations involved in air program management; and other State and local governments.

While there were some differences across commenters, a majority of the commenters support use of next generation data for non-regulatory purposes, but not for regulatory decision making due to their inherent uncertainties and limitations. The EPA also received comments from some environmental organizations support using alternative data for regulatory decision making.

[199] Available at *https://fire.airnow.gov/*.

Many commenters pointed out that they are already successfully using sensor data and networks in supplemental and informational applications and support further expansion of these capabilities. Across many commenters, there was support for using next generation data as ''fit for purpose,'' filling in gaps, finding hot spots, identifying and addressing EJ concerns, and evaluating and informing network siting. The EPA acknowledges the successful examples of sensor data and networks for non-regulatory purposes. A few commenters support expanding the use of sensor data to provide real-time AQI; the EPA is interested in this use of next generation data as well. A few commenters pointed the need for the EPA to work closely with them and their communities to understand and use next generation data, while others expressed a desire for help developing best practices around collecting and using next generation data, developing products with data analysis/visualization, and developing appropriate QA/QC for sensor data. The EPA acknowledges each of these requests and expects to continue to work closely with SLTs and other stakeholders to understand and develop information on the collection and use of next generation data.

A few commenters offered more detailed comments. Some recommended that the EPA repropose implementation provisions related to next generation technologies with greater clarity to provide for meaningful comment. For example, the use of low-cost sensor and satellite data could be used in drawing nonattainment area boundaries or identifying sources for emissions control, but doing so would be such a significant change from prior EPA policy that it warrants a more specific proposal, beyond the scope of this request for comment. In response to this comment, the EPA notes it did not propose or change the use of non-regulatory measurement data as part of this proposal, but instead opened an opportunity to comment about the use of next generation technologies.

Another commenter stated that while low-cost sensor data can be invaluable for some purposes, the potentially overwhelming amount of data produced by sensors may present additional challenges to communities without the resources or expertise to analyze it. Cost is another concern associated with some next generation technologies of which some communities may not be aware, as the initial cost of the sensor alone is not indicative of the total cost of operation, which can include costs of internet access and servers. The EPA appreciates the need to consider all the costs of implementing and maintaining sensor data.

Another commenter stated that having a dense sensor network collocated with FRMs and FEMs could help ensure timely maintenance of the regulatory measurements in the event there appears to be a divergence of data. The EPA appreciates the comment that emphasizes how sensors could be used to complement the FRM and FEM data with regard to ensuring timely maintenance.

Another commentor strongly opposes incorporating sensor data into any EPA systems unless robust quality assurance (QA) practices are widely established and managed by qualified personnel. The EPA agrees that QA is necessary, and notes that the ''fit for purpose'' aspect of using sensor data will inform the appropriate QA associated with the intended use of such data.

In summary, the EPA invited comment on how we should consider incorporating data from next generation technologies into our air monitoring efforts. In seeking comment on this topic, the EPA did not propose to add, edit, or delete any regulatory language associated with the PM NAAQS. The EPA received comments from a variety of entities that largely support using next generation data for a variety of purposes that supplement, but cannot replace, the measurement data from monitoring methods required (*i.e.,* FRMs and FEMs) for regulatory decision making. Across many commenters, there was support for using next generation technologies and data as ''fit for purpose,'' filling in gaps, finding hot spots, identifying, and addressing EJ concerns, and evaluating and informing network siting. Quality assurance of the data will be an important component in the use of next generation technology data. The EPA will consider these comments as it continues its work with the co-regulated community comprised of SLT agencies and other stakeholders to understand and use next generation data and joint efforts to manage the nation's ambient air.

VIII. Clean Air Act Implementation Requirements for the Revised Primary Annual $PM_{2.5}$ NAAQS

The EPA's revision to the primary annual $PM_{2.5}$ NAAQS discussed in section II above triggers a number of implementation related activities that were described in the NPRM. The two most immediate implementation impacts following a final new or revised NAAQS are related to stationary source permitting and the initial area designations process. Permitting implications are discussed below in section VIII.E. With regard to initial area designations, the EPA is separately issuing a memorandum regarding the Initial Area Designations for the Revised Primary Annual Fine Particle National Ambient Air Quality Standard Memorandum (the ''Annual $PM_{2.5}$ NAAQS Designations Memorandum'') that will provide information about the statutory schedule for the designations process. For other implementation related implications, please refer back to the NPRM section VIII.

The NPRM also referred to the $PM_{2.5}$ State Implementation Plan (SIP) Requirements Rule (81 FR 58010, August 24, 2016), which specifies planning requirements for areas designated as nonattainment for purposes of the $PM_{2.5}$ NAAQS and includes a number of key recommendations for areas to consider implications of environmental justice through the attainment planning process, consistent with the identification of at-risk groups in the 2019 ISA and ISA Supplement and the statutory requirement to protect the health of at-risk groups. As stated in the NPRM, State and local air agencies are encouraged to consider how they might develop implementation plans that encourage early emission reductions.

A. Designation of Areas

As discussed in section II, with respect to the $PM_{2.5}$ NAAQS, the EPA is finalizing: (1) Revisions to the level of the primary annual $PM_{2.5}$ NAAQS and retaining the current primary 24-hour $PM_{2.5}$ NAAQS (section II.B.4); and (2) no change to the current secondary annual and 24-hour $PM_{2.5}$ NAAQS at this time (section V.B.4). Upon promulgation of a new or revised NAAQS, States and the EPA must initiate the process for initial designations.

The timeline for initial area designations begins with promulgation of the revised primary annual $PM_{2.5}$ NAAQS, as stated in the CAA section 107(d)(1)(B)(i). Through this process, which provides for input from States and others at various stages, the EPA identifies areas of the country that either meet or do not meet the revised primary annual $PM_{2.5}$ NAAQS, along with the nearby areas contributing to NAAQS violations. The following includes additional information regarding the designations process described in the CAA.

Section 107(d)(1) of the CAA states that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section

109, the Governor of each State shall . . . submit to the Administrator a list of all areas (or portions thereof) in the State'' and make recommendations for whether the EPA should designate those areas as nonattainment, attainment, or unclassifiable.[200] The CAA provides the EPA with discretion to require States to submit their designations recommendations within a reasonable amount of time not exceeding one additional year.[201] Section 107(d)(1)(A) of the CAA also states that ''the Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard.'' Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) . . . as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' With respect to the NAAQS setting process, courts have interpreted the term ''promulgation'' to be signature and widespread dissemination of a final rule.[202]

If the EPA agrees with the designations recommendation of the State, then it may proceed to promulgate the designations for such areas. If, however, the EPA disagrees with the State's recommendation, then the EPA may elect to make modifications to the recommended designations. By no later than 120 days prior to promulgating the final designations, the EPA is required to notify States of any intended modifications to the State designation recommendations for any areas or portions thereof, including the boundaries of areas, as the EPA may deem necessary. States then have an opportunity to comment on the EPA's intended modification and tentative designation decision. If a State elects not to provide designation recommendations for any area, then the EPA must itself promulgate the designation that it deems appropriate.

While section 107(d) of the CAA specifically addresses the designations process for States, the EPA intends to follow the same process for Tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding Tribal authority, and the Tribal Authority Rule (63 FR 7254, February 12, 1998). To provide clarity and consistency in doing so, the EPA issued a guidance memorandum to our Regional Offices on working with Tribes during the designations process.[203]

Consistent with the process used in previous area designations efforts, the EPA will evaluate each area on a case-by-case basis considering the specific facts and circumstances unique to the area to support area boundary decisions for the revised standard. The EPA intends to issue a designations memorandum which will provide information regarding the designations process. In broad overview, the EPA has historically used area-specific analyses to support nonattainment area boundary recommendations and final boundary determinations by evaluating factors such as air quality data, emissions and emissions-related data (*e.g.,* population density and degree of urbanization, traffic and commuting patterns), meteorology, geography/topography, and jurisdictional boundaries. We expect to follow a similar process when establishing area designations for this revised $PM_{2.5}$ NAAQS. CAA section 107(d) explicitly requires that the EPA designate as nonattainment not only the area that is violating the pertinent standard, but also those nearby areas that contribute to the violation in the violating area. In the $PM_{2.5}$ NAAQS Designations Memorandum, the EPA intends to include information regarding consideration of federal land boundaries that may be fully or partially included within the bounds of a county otherwise identified as nonattainment.

As with past revisions of the $PM_{2.5}$ NAAQS, the EPA intends to make the designations decisions for the revised primary annual $PM_{2.5}$ NAAQS based on the most recent three years of quality-assured, certified air quality data in the EPA's Air Quality System (AQS). Accordingly, the EPA recommends that States base their initial area designation recommendations on the most current available three years of complete and certified air quality data at the time of the recommendations. The EPA will then base the final designations on the most recent three consecutive years of complete, certified air quality monitoring data available at the time of final designations.[204]

Monitoring data are currently available from numerous existing $PM_{2.5}$ Federal Equivalent Methods (FEM) and Federal Reference Methods (FRM) sites to determine violations of the revised primary annual $PM_{2.5}$ NAAQS. As described in section VII.C.3.b, the EPA took comment on how to deal with cases where an FEM is approved by the EPA with an update and when it can be implemented in the field. The EPA took comment on how to approach the data produced during this lag and received input from over a dozen commenters. The commenters asked that the EPA be flexible in allowing the use of updated method correction factors intended to improve the data comparability between the FRMs and FEMs. The EPA will address any data correction issues between the FRMs and FEMs through a future Notice of Data Availability (NOA).

Consistent with past practice and as noted in the NPRM, the EPA intends to provide additional information concerning the designations process, including information about the schedule and recommendations for determining area boundaries in the forthcoming Annual $PM_{2.5}$ NAAQS Designations Memorandum. Other topics addressed in this memorandum include the schedule for preparing and submitting exceptional events initial notification and exceptional events demonstrations relevant to the designations process, and information related to wildfire and prescribed fire on wildlands as it pertains to initial area designations, as well as addressing back-correction of PM FEM data when a method has an approved factory calibration as part of a method update. The Annual $PM_{2.5}$ NAAQS Designations Memorandum is intended to assist States and Tribes in formulating their area recommendations.[205]

As discussed in the proposal, the ''Treatment of Data Influenced by Exceptional Events; Final Rule,'' (81 FR 68216, October 3, 2016) and codified at 40 CFR 50.1, 40 CFR 50.14, and 40 CFR 51.930, contains instructions and requirements for air agencies that may

[200] While the CAA says ''designating'' with respect to the Governor's letter, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.

[201] In certain circumstances in which the Administrator has insufficient information to promulgate area designations within two years from the promulgation of the NAAQS, CAA section 107(d)(1)(B)(i) provides that the EPA may extend the designations schedule by up to one year.

[202] *API* v. *Costle,* 609 F.2d 20 (D.C. Cir. 1979).

[203] ''Guidance to Regions for Working with Tribes during the National Ambient Air Quality Standards (NAAQS) Designations Process,'' December 20, 2011, Memorandum from Stephen D. Page to Regional Air Directors, Regions 1–X available at *https://www.epa.gov/sites/default/files/2017-02/documents/12-20-11_guidance_to_regions_for_working_with_tribes_naaqs_designations.pdf.*

[204] In certain circumstances in which the Administrator has insufficient information to promulgate area designations within two years from the promulgation of a new or revised NAAQS, CAA section 107(d)(1)(B)(i) provides the EPA may extend the designations schedule by up to one year.

[205] See: *https://www.epa.gov/particle-pollution-designations.*

flag air quality data for certain days in the Air Quality System due to potential impacts from exceptional events (*i.e.,* such as prescribed fires on wildland, wildfires, or high wind dust storms). Accordingly, for purposes of initial area designations for a new or revised NAAQS, an air agency may submit to the EPA an exceptional events demonstration with supporting information and analyses for each monitoring site and day the air agency claims the EPA should exclude from design value calculations for designations purposes.

The EPA has provided tools to assist air agencies in preparing adequate exceptional events demonstrations.[206] Further, the EPA will continue to work with air agencies as they identify exceptional events that may influence decisions related to the initial area designations process, and to prepare and submit exceptional events demonstrations if appropriate. Importantly, air quality monitoring data may be influenced by emissions from prescribed fires on wildland and wildfires. The EPA's Exceptional Events Rule provides for both of these types of events to be considered as exceptional events, provided the affected air agencies submit exceptional events demonstrations that meet the procedural and technical requirements of the EPA's Exceptional Events Rule. To that end, the EPA has issued guidance addressing development of exceptional events demonstrations for both wildfire and prescribed fires on wildland.[207] In light of the growing frequency and severity of wildfire events, and expected increases in the application of prescribed fire as a means to achieve long-term reductions in high severity wildfire risk and associated smoke impacts, the EPA seeks to ensure that the Agency's exceptional events process provides an efficient and clear pathway for excluding data that may be affected by such events in a manner that is consistent with the Clean Air Act and the public health objectives of the NAAQS. Accordingly, the EPA is continuing to explore opportunities to develop additional tools that could assist air agencies in preparing exceptional events demonstrations for wildfires and prescribed fires on wildland. In addition, EPA intends to continue engaging with the U.S. Department of Agriculture, U.S. Department of the Interior, air agencies, and other stakeholders on these issues. For more information regarding the exceptional events demonstration submission deadlines for the area designations process, please see Table 2 to 40 CFR 50.14(c)(2)(vi)—''Schedule for Initial Notification and Demonstration Submission for Data Influenced by Exceptional Events for Use in Initial Area Designations.''

B. Section 110(a)(1) and (2) Infrastructure SIP Requirements

As discussed in the NPRM, the CAA directs States to address basic SIP requirements to implement, maintain, and enforce the NAAQS. Under CAA sections 110(a)(1) and (2), states are required to have State implementation plans that provide the necessary air quality management infrastructure that provides for the implementation, maintenance, and enforcement of the NAAQS. After the EPA promulgates a new or revised NAAQS, States are required to make a new SIP submission to establish that they meet the necessary structural requirements for such new or revised NAAQS or make changes to do so. The EPA refers to this type of SIP submission as an ''infrastructure SIP submission.'' Under CAA section 110(a)(1), all States are required to make these infrastructure SIP submissions within three years after the effective date of a new or revised primary standard. While the CAA authorizes the EPA to set a shorter time for States to make these SIP submissions, the EPA is requiring submission of infrastructure SIPs within three years of the effective date of this revised primary annual $PM_{2.5}$ NAAQS.

The EPA has provided general guidance to States concerning its interpretation of these requirements of CAA section 110(a)(1) and (2) in the context of infrastructure SIP submissions for a new or revised NAAQS.[208] The EPA encourages States to use this guidance when developing their infrastructure SIPs for this revised primary annual $PM_{2.5}$ NAAQS.

As a reminder, the EPA notes that States are not required to address nonattainment plan requirements for purposes of the revised primary annual $PM_{2.5}$ NAAQS on the same schedule as infrastructure SIP requirements. The EPA interprets the CAA such that two elements identified in section 110(a)(2) are not subject to the 3-year submission deadline of section 110(a)(1) and thus States are not required to address them in the context of an infrastructure SIP submission. The elements pertain to part D, in title I of the CAA, which addresses additional SIP requirements for nonattainment areas. Therefore, for the reasons explained below, the following section 110(a)(2) elements are considered by the EPA to be outside the scope of infrastructure SIP actions: (1) The portion of section 110(a)(2)(C), programs for enforcement of control measures and for construction or modification of stationary sources that applies to permit programs applicable in designated nonattainment areas (known as ''nonattainment new source review'') under part D; and (2) section 110(a)(2)(I), which requires a SIP submission pursuant to part D, in its entirety.

Accordingly, the EPA does not expect States to address the requirement for a new or revised NAAQS in the infrastructure SIP submissions to include regulations or emissions limits developed specifically for attaining the relevant standard in areas designated nonattainment for the revised primary annual $PM_{2.5}$ NAAQS. States are required to submit infrastructure SIP submissions for the revised primary annual $PM_{2.5}$ NAAQS before they will be required to submit nonattainment plan SIP submissions to demonstrate attainment with the same NAAQS. States are required to submit nonattainment plan SIP submissions to provide for attainment and maintenance of a revised primary annual $PM_{2.5}$ NAAQS within 18 months from the effective date of nonattainment area designations as required under CAA section 189(a)(2)(B). The EPA reviews and acts upon these later SIP submissions through a separate process. For this reason, the EPA does not expect States to address new nonattainment area emissions controls per section 110(a)(2)(I) in their infrastructure SIP submissions.

One of the required infrastructure SIP elements is that each State SIP must contain adequate provisions to prohibit, consistent with the provisions of title I of the CAA, emissions from within the State that will significantly contribute to nonattainment in, or interfere with maintenance by, any other State of the primary or secondary NAAQS.[209] This

[206] See the EPA's Exceptional Events homepage at *https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional.*

[207] See EPA's ''Final Guidance on the Preparation of Exceptional Events Demonstrations for Wildfire Events that May Influence Ozone Concentrations and EPA's Exceptional Events Guidance: Prescribed Fire on Wildland that May Influence Ozone and Particulate Matter Concentrations,'' found on EPA's Exceptional Events homepage at *https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional.*

[208] *See* ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' September 2013, Memorandum from Stephen D. Page to Regional Air Directors, Regions 1–10.

[209] CAA section 110(a)(2)(D)(i)(I).

element is often referred to as the ''good neighbor'' or ''interstate transport'' provision.[210] The provision has two prongs: significant contribution to nonattainment (prong 1), and interference with maintenance (prong 2). The EPA and States must give independent significance to prong 1 and prong 2 when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).[211] Further, case law has established that the EPA and States must implement requirements to meet interstate transport obligations in alignment with the applicable statutory attainment schedule of the downwind areas impacted by upwind-state emissions.[212] Thus, the EPA anticipates that States will need to address interstate transport obligations associated with this revised PM NAAQS, in alignment with the provisions of subpart 4 of part D of the CAA, as discussed in more detail in section VIII.C below. Specifically, States must implement any measures required to address interstate transport obligations as expeditiously as practicable and no later than the next statutory attainment date, *i.e.,* for this NAAQS revision as expeditiously as practicable, but no later than the end of the sixth calendar year following nonattainment area designations. *See* CAA section 188(c). States may find it efficient to make SIP submissions to address the interstate transport provisions separately from other infrastructure SIP elements.

Each State has the authority and responsibility to review its air quality management program's existing SIP provisions in light of a new or revised NAAQS to determine if any revisions are necessary to implement the new or revised NAAQS. Most States have revised and updated their SIPs in recent years to address requirements associated with other revised NAAQS. For certain infrastructure elements, some States may believe they already have adequate State regulations adopted and approved into the SIP to address a particular requirement with respect to the revised primary annual $PM_{2.5}$ NAAQS.

If a State determines that existing SIP-approved provisions are adequate in light of this revised primary annual $PM_{2.5}$ NAAQS with respect to a given infrastructure SIP element (or sub-element), then the State may make an infrastructure SIP submission ''certifying'' that the existing State's existing EPA approved SIP already contains provisions that address one or more specific section 110(a)(2) infrastructure elements.[213] In the case of such a submission, the State does not have to include a copy of the relevant provision (*e.g.,* rule or statute) itself. Rather, this certification submission should provide citations to the SIP-approved State statutes, regulations, or non-regulatory measures, as appropriate, in or referenced by the already EPA-approved SIP that meet particular infrastructure SIP element requirements. The State's infrastructure SIP submission should also include an explanation as to how the State has determined that those existing provisions meet the relevant requirements.

Like any other SIP submission, that State can make such an infrastructure SIP submission certifying that it has already met some or all of the applicable requirements only after it has provided reasonable notice and opportunity for public hearing. This ''reasonable notice and opportunity for public hearing'' requirement for infrastructure SIP submissions is to meet the requirements of CAA sections 110(a) and 110(l). Under the EPA's regulations at 40 CFR part 51, if a public hearing is held, an infrastructure SIP submission must include a certification by the State that the public hearing was held in accordance with the EPA's procedural requirements for public hearings. See 40 CFR part 51, appendix V, section 2.1(g), and see 40 CFR 51.102.

In consultation with the EPA's Regional office, a State should follow all applicable EPA regulations governing infrastructure SIP submissions in 40 CFR part 51—*e.g.,* subpart I (Review of New Sources and Modifications), subpart J (Ambient Air Quality Surveillance), subpart K (Source Surveillance), subpart L (Legal Authority), subpart M (Intergovernmental Consultation), subpart O (Miscellaneous Plan Content Requirements), subpart P (Protection of Visibility), and subpart Q (Reports). For the EPA's general criteria for infrastructure SIP submissions, refer to 40 CFR part 51, appendix V, Criteria for Determining the Completeness of Plan Submissions. For additional information on infrastructure SIP submission requirements, refer to the EPA's 2013 guidance entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2).'' The EPA recommends that States electronically submit their infrastructure SIPs to the EPA through the State Plan Electronic Collaboration System (SPeCS),[214] an online system available through the EPA's Central Data Exchange.

C. Implementing Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

As discussed in the NPRM, the EPA issued a SIP Requirements Rule for implementing the $PM_{2.5}$ NAAQS (81 FR 58010, August 24, 2016) ($PM_{2.5}$ SIP Requirements Rule). It provides guidance and establishes additional regulatory requirements for States regarding development of attainment plans for nonattainment areas for the 1997, 2006, and 2012 revisions of the $PM_{2.5}$ NAAQS. The guidance and regulations in the SIP Requirements Rule also apply to any States for which the EPA promulgates nonattainment area designations for the new revised primary annual $PM_{2.5}$ NAAQS.

The $PM_{2.5}$ SIP Requirements Rule provides comprehensive information regarding nonattainment plan requirements including, among other things: nonattainment area emissions inventories; policies regarding $PM_{2.5}$ precursor pollutants (*i.e.,* SO_2, NO_X, VOC, and ammonia); control strategies (such as reasonably available control measures and reasonably available control technology for direct $PM_{2.5}$ and relevant precursors); air quality modeling; attainment demonstrations; reasonable further progress requirements; quantitative milestones; and contingency measures. Information provided in the $PM_{2.5}$ SIP Requirements Rule is supplemented by other EPA documents, including guidance on emissions inventory development (80 FR 8787, February 19, 2015; U.S. EPA, 2017), optional $PM_{2.5}$ precursor demonstrations (U.S. EPA, 2019b),[215] and guidance on air quality modeling for meeting air quality goals for the ozone and $PM_{2.5}$ NAAQS and regional haze program (U.S. EPA, 2018b).

As stated in the NPRM, the $PM_{2.5}$ SIP Requirements Rule provides recommendations to States regarding consideration of environmental justice in the context of $PM_{2.5}$ attainment

[210] CAA section 110(a)(2)(D)(i)(II) also addresses certain interstate effects that states must address and thus is also sometimes referred to as relating to ''interstate transport.''

[211] *See North Carolina* v. *EPA,* 531 F.3d 896, 909–11 (D.C. Cir. 2008).

[212] *See id.* 911–13. *See also Wisconsin* v. *EPA,* 938 F.3d 303, 313–20 (D.C. Cir. 2019); *Maryland* v. *EPA,* 958 F.3d 1185, 1203–04 (D.C. Cir. 2020).

[213] A ''certification'' approach would not be appropriate for the interstate pollution control requirements of CAA section 110(a)(2)(D)(i).

[214] *https://cdx.epa.gov/.*

[215] Provides guidance on developing demonstrations under section 189(e) intended to show that a certain $PM_{2.5}$ precursor in a particular nonattainment area does not significantly contribute to $PM_{2.5}$ concentrations that exceed the standard.

planning. Some of the considerations for States include: (1) Identifying areas with overburdened communities where more ambient monitoring may be warranted; (2) targeting emissions reductions that may be needed to attain the $PM_{2.5}$ NAAQS; and (3) increasing opportunities for meaningful involvement for overburdened populations (*see* 88 FR 5558, 5684, January 27, 2023; 80 FR 58010, 58136, August 25, 2016). In light of the identification of at-risk populations for this reconsideration, the EPA encourages States to consider these and other factors as part of their attainment plan SIP development process.

The $PM_{2.5}$ SIP Requirements Rule outlines some examples of how States can elect to implement these recommendations.[216] For instance, States can use modeling and screening tools to better understand where sources of $PM_{2.5}$ or $PM_{2.5}$ precursor emissions are located and identify areas that may be candidates for additional ambient monitoring. Furthermore, once these target areas are identified, States can prioritize direct $PM_{2.5}$ or $PM_{2.5}$ precursor control measures and enforcement strategies in these areas to reduce ambient $PM_{2.5}$ and achieve the NAAQS. As articulated in the NPRM and the $PM_{2.5}$ SIP Requirements Rule, the EPA recognizes that States have flexibility under the CAA to concentrate State resources on controlling sources of $PM_{2.5}$ emissions in light of environmental justice considerations (*see* 88 FR 5558, 5684, January 27, 2023; 81 FR 58010, 58137, August 24, 2016). Moreover, States can establish opportunities to bolster meaningful involvement in a number of ways, such as communicating in appropriate languages, ensuring access to draft SIPs and other information, and developing enhanced notice-and-comment opportunities, as appropriate (*see* 88 FR 5558, 5684, January 27, 2023; 80 FR 58010, 58136, August 25, 2016).

As previously mentioned, the $PM_{2.5}$ SIP Requirements Rule provides guidance and regulatory requirements for remaining nonattainment areas for the 1997, 2006, and 2012 revisions of the $PM_{2.5}$ NAAQS, as well as for nonattainment areas designated pursuant to any future revisions of the $PM_{2.5}$ NAAQS, including the revised annual $PM_{2.5}$ NAAQS being finalized in this action. The EPA is not making any changes to the current $PM_{2.5}$ SIP Requirements Rule.

[216] For more information on the EPA's recommendations and examples, *see* 81 FR 58010, 58137, August 24, 2016.

D. Implementing the Primary and Secondary PM_{10} NAAQS

As summarized in sections III.B.4 and V.B.4 above, the EPA is retaining the current primary and secondary 24-hour PM_{10} NAAQS to protect against the health effects associated with short-term exposures to thoracic coarse particles and against the welfare effects considered in this reconsideration (*i.e.,* visibility, climate, and materials effects). The EPA is retaining the existing implementation strategy for meeting the CAA requirements for the PM_{10} NAAQS. States and emissions sources should continue to follow the existing regulations and guidance for implementing the current standards.[217]

E. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Revised Primary Annual $PM_{2.5}$ NAAQS

The CAA, at parts C and D of title I, contains preconstruction review and permitting programs applicable to new major stationary sources and major modifications of existing major sources. The preconstruction review of each new major stationary source and major modification applies on a pollutant-specific basis, and the requirements that apply for each pollutant depend on whether the area in which the source is situated is designated as attainment (or unclassifiable) or nonattainment for that pollutant. In areas designated attainment or unclassifiable for a pollutant, the Prevention of Significant Deterioration (PSD) requirements under part C apply to construction at major sources. In areas designated nonattainment for a pollutant, the Nonattainment New Source Review (NNSR) requirements under part D apply to construction at major sources. Collectively, those two sets of permit requirements are commonly referred to as the ''major New Source Review'' or ''major NSR'' programs.

Until the EPA designates an area with respect to the revised primary annual $PM_{2.5}$ NAAQS, the NSR provisions applicable under an area's current designation for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS would continue to apply. *See* 40 CFR 51.166(i)(2) and 52.21(i)(2). That is, for areas designated as attainment/unclassifiable for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS, PSD will apply to new major stationary sources and major modifications that trigger major source permitting requirements for $PM_{2.5.}$ For areas designated nonattainment for the 1997, 2006, or 2012 $PM_{2.5}$ NAAQS, NNSR requirements will apply for new major stationary sources and major modifications that trigger major source permitting requirements for $PM_{2.5}$. When the initial area designations for this revised primary annual $PM_{2.5}$ NAAQS become effective, those designations will further determine whether PSD or NNSR applies to $PM_{2.5}$ in a particular area, depending on the designation status. New major sources and major modifications will be subject to the PSD program requirements for $PM_{2.5}$ if they are located in an area that does not have a current nonattainment designation under CAA section 107 for $PM_{2.5}$.[218]

Under the PSD program, the permit applicant must demonstrate that the new or modified source emissions increase does not cause or contribute to a NAAQS violation. In 2017, the EPA revised the *Guideline on Air Quality Models* (published as appendix W to 40 CFR part 51) to address primary and secondary $PM_{2.5}$ impacts in making this demonstration. The EPA has since provided associated technical guidance, models and tools, such as the recent ''Final Guidance for Ozone and Fine Particulate Matter Permit Modeling'' (July 29, 2022).[219] Additionally, in light of this NAAQS revision, the EPA is updating its guidance that provides recommended significant impact levels (SILs) for $PM_{2.5}$ and expects that an updated SIL for the revised primary annual $PM_{2.5}$ NAAQS will be available

[217] CAA Sections 110(a) and 172 contain general nonattainment planning provisions, regarding the public review, adoption, submittal, and content of implementation plans. CAA Section 189 specifies additional plan provisions for particulate matter nonattainment areas. General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990 provides a detailed discussion of the EPA's interpretation of the Title I requirements (57 FR 13498, April 16, 1992; 59 FR 41998, August 16, 1994).

[218] 40 CFR 51.166(i)(2) and 52.21(i)(2).

[219] On July 29, 2022, the EPA issued ''Final Guidance for Ozone and Fine Particulate Matter Permit Modeling,'' available at *https://www.epa.gov/system/files/documents/2022-07/Guidance_for_O3_PM25_Permit_Modeling.pdf.* This guidance provides the EPA's recommendations for how a stationary source seeking a PSD permit may demonstrate that it will not cause or contribute to a violation of the National Ambient Air Quality Standards for Ozone and $PM_{2.5}$ and PSD increments for $PM_{2.5}$, as required under section 165(a)(3) of the Clean Air Act and 40 CFR 51.166(k) and 52.21(k). The EPA has also previously issued two technical guidance documents for use in conducting these demonstrations: ''Guidance on the Development of Modeled Emission Rates for Precursors (MERPs) as a Tier 1 Demonstration Tool for Ozone and $PM_{2.5}$ under the PSD Permitting Program,'' available at *https://www.epa.gov/sites/default/files/2020-09/documents/epa-454_r-19-003.pdf,* and ''Guidance on the Use of Models for Assessing the Impacts of Emissions from Single Sources on the Secondarily Formed Pollutants: Ozone and $PM_{2.5}$,'' available at *https://www.epa.gov/sites/default/files/2020-09/documents/epa-454_r-16-005.pdf.*

on or before the effective date of the final NAAQS.

The statutory requirements for a PSD permit program set forth under part C of title I of the CAA (sections 160 through 169) are addressed by the EPA's PSD regulations found at 40 CFR 51.166 (minimum requirements for an approvable PSD SIP) and 40 CFR 52.21 (PSD permitting program for permits issued under the EPA's Federal permitting authority). These regulations already apply to $PM_{2.5}$ in areas that are designated attainment or unclassifiable for $PM_{2.5}$ whenever a proposed new major source or major modification triggers PSD requirements for $PM_{2.5}$.

For PSD, a ''major stationary source'' is one with the potential to emit 250 tons per year (tpy) or more of any regulated NSR pollutant, unless the new or modified source is classified under a list of 28 source categories contained in the statutory definition of ''major emitting facility'' in section 169(1) of the CAA. For those 28 source categories, a ''major stationary source'' is one with the potential to emit 100 tpy or more of any regulated NSR pollutant. A ''major modification'' is a physical change or a change in the method of operation of an existing major stationary source that results, first, in a significant emissions increase of a regulated NSR pollutant and, second, in a significant net emissions increase of that pollutant. See 40 CFR 51.166(b)(2)(i), 40 CFR 52.21(b)(2)(i). The EPA PSD regulations define the term ''regulated NSR pollutant'' to include any pollutant for which a NAAQS has been promulgated and any pollutant identified by the EPA as a constituent or precursor to such pollutant. See 40 CFR 51.166(b)(49), 40 CFR 52.21(b)(50). These regulations identify SO_2 and NO_X as precursors to $PM_{2.5}$ in attainment and unclassifiable areas. See 40 CFR 51.166(b)(49)(i)(b), 40 CFR 52.21(b)(50)(i)(b).[220] Thus, for $PM_{2.5}$, the PSD program currently requires the review and control of emissions of direct $PM_{2.5}$ emissions and SO_2 and NO_X (as precursors to $PM_{2.5}$), absent a demonstration otherwise for NO_X. Among other things, for each regulated NSR pollutant emitted or increased in a significant amount, the PSD program requires a new major stationary source or a major modification to apply the ''best available control technology'' (BACT) to limit emissions and to conduct an air quality impact analysis to demonstrate that the proposed major stationary source or major modification will not cause or contribute to a violation of any NAAQS or PSD increment.[221] See CAA section 165(a)(3) and (4), 40 CFR 51.166(j) and (k), 40 CFR 52.21(j) and (k). The PSD requirements may also include, in appropriate cases, an analysis of potential adverse impacts on Class I areas. See CAA sections 162(a) and 165(d), 40 CFR 51.166(p); 40 CFR 52.21(p)).[222] The EPA developed the Guideline on Air Quality Models and other documents to, among other things, provide methods and guidance for demonstrating that increased emissions from construction will not cause or contribute to exceedances of the $PM_{2.5}$ NAAQS and PSD increments for $PM_{2.5}$.[223]

Upon the effective date of the revised primary annual $PM_{2.5}$ NAAQS, the demonstration required under CAA Section 165(a)(3), and the associated regulations, must include the revised primary annual $PM_{2.5}$ NAAQS. In past NAAQS revision rules, including the 2012 $PM_{2.5}$ NAAQS (78 FR 3086, January 15, 2013) and 2015 Ozone NAAQS (80 FR 65292, October 26, 2015), the EPA included limited provision that exempted certain sources with pending PSD permit applications (those that had reached a particular stage in the permitting process at the time the revised NAAQS was promulgated or became effective) from the requirement to demonstrate that the proposed emissions increases would not cause or contribute to a violation of the revised NAAQS.[224] In August 2019, the U.S. Court of Appeals for the D.C. Circuit vacated the exemption provision in the PSD rules for the 2015 Ozone NAAQS, finding that the provision contradicted ''Congress's 'express policy choice' not to allow construction which will 'cause or contribute to' nonattainment of 'any' effective NAAQS, regardless of when they are adopted or when a permit was completed.'' *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 627 (D.C. Cir. 2019).[225] Based on that court decision, the EPA is not establishing any PSD permitting exemption provision in this action. Some commenters requested that the EPA provide the same kind of relief for pending PSD permit applications by extending the effective date of this new revised NAAQS beyond the 60 days that the EPA has traditionally used for such rules. Such comments are addressed in the Response to Comments portion of this action. The EPA is making this revised primary annual $PM_{2.5}$ NAAQS effective in 60 days.

The EPA anticipates that the existing $PM_{2.5}$ air quality in some areas will not be in attainment with the revised primary annual $PM_{2.5}$ NAAQS, and the EPA will designate these areas as nonattainment at a later date, consistent with the designation process described in the preceding sections. However, until such nonattainment designation occurs, proposed new major sources and major modifications located in any area currently designated attainment or unclassifiable for all preexisting $PM_{2.5}$ NAAQS will continue to be subject to the PSD program requirements for $PM_{2.5}$. Any proposed major stationary source or major modification triggering PSD requirements for $PM_{2.5}$ that does not receive its PSD permit by the effective date of a new nonattainment designation for the area where the source would locate would then be required to satisfy applicable NNSR preconstruction permit requirements for $PM_{2.5}$.

In areas where air pollution exceeds the level of the revised primary annual $PM_{2.5}$ NAAQS, a PSD permit applicant must demonstrate that the source or modification will not cause or

[220] Sulfur dioxide is a precursor to $PM_{2.5}$ in all attainment and unclassifiable areas. NO_X is presumed to be a precursor to $PM_{2.5}$ in all attainment and unclassifiable areas, unless a state or the EPA demonstrates that emissions of NO_X from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations. VOC is presumed not to be a precursor to $PM_{2.5}$ in any attainment or unclassifiable area, unless a state or the EPA demonstrates that emissions of VOC from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

[221] By establishing the maximum allowable level of ambient pollutant concentration increase in a particular area, an increment defines ''significant deterioration'' of air quality in that area. Increments are defined by the CAA as maximum allowable increases in ambient air concentrations above a baseline concentration and are specified in the PSD regulations by pollutant and area classification (Class I, II and III). 40 CFR 51.166(c), 40 CFR 52.21(c); 75 FR 64864 (October 20, 2010).

[222] Congress established certain Class I areas in section 162(a) of the CAA, including international parks, national wilderness areas, and national parks that meet certain criteria. Such Class I areas, known as mandatory Federal Class I areas, are afforded special protection under the CAA. In addition, States and Tribal governments may establish Class I areas within their own political jurisdictions to provide similar special air quality protection.

[223] *See* 40 CFR part 51, appendix W; 82 FR 5182 (January 17, 2017); *See also* U.S. EPA, 2021d. The EPA provided an initial version of the 2021 guidance for public comment on February 10, 2020. Upon consideration of the comments received, and consistent with Executive Order 13990, the EPA revised the initial draft guidance and posted the revised version for additional public comment.

[224] This exemption was referred to as ''grandfathering'' in the 2015 Ozone NAAQS and the D.C. Circuit's *Murray Energy Corp.* decision on that exemption. *See* 80 FR 65292, 65431 (October 26, 2015); *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 627 (D.C. Cir. 2019). The EPA refers to this ''grandfathering'' provision in this action as an exemption provision.

[225] While the specifics of this case involved the 2015 ozone NAAQS, the case was based upon an interpretation of CAA section 165(a) and therefore applies equally to any PSD permitting exemption provision for a new or revised NAAQS.

contribute to a violation of the NAAQS. Section 165(a)(3)(B) of the CAA states that a proposed source may not construct unless it demonstrates that it will not cause or contribute to a violation of any NAAQS. This statutory requirement is implemented through a provision contained in the PSD regulations at 40 CFR 51.166(k) and 52.21(k).[226] If a source cannot make this demonstration, or if its initial air quality impact analysis shows that the source's impact would cause or contribute to a violation, the reviewing authority may not issue a PSD permit to that source. However, a PSD permit applicant may be able to make this demonstration if it compensates for the adverse impact that would otherwise cause or contribute to a violation of the NAAQS. In contrast to the NSR requirements for nonattainment areas, the PSD regulations do not explicitly specify remedial actions that a prospective source must take to address such a situation, but the EPA has historically recognized that sources applying for PSD permits may utilize offsetting reductions in emissions as part of the required PSD demonstration under CAA section 165(a)(3)(B).[227]

Part D of title I of the CAA includes preconstruction review and permitting requirements applicable to new major stationary sources and major modifications located in areas designated nonattainment for a pollutant for which the EPA has established a NAAQS (*i.e.,* a criteria pollutant). The relevant part D requirements are typically referred to as the nonattainment NSR (NNSR) program. The EPA's regulations for the NNSR program are contained in 40 CFR 51.165 and 52.24 and part 51, appendix S. Specifically, the EPA has developed minimum program requirements for a NNSR program that is approvable in a SIP, and those requirements, which include requirements for $PM_{2.5}$, are contained in 40 CFR 51.165. In addition, 40 CFR part 51, appendix S, contains requirements constituting an interim NNSR program. This interim program enables NNSR permitting in nonattainment areas by States that lack a SIP-approved NNSR permitting program during the time between the date of the relevant designation and the date that the EPA approves into the SIP a NNSR program. *See* 40 CFR part 51, appendix S, section I; 40 CFR 52.24(k).

For NNSR, ''major stationary source'' is generally defined as a source with the potential to emit at least 100 tpy of the regulated NSR pollutant for which the area is designated nonattainment. In some cases, however, the CAA and the NNSR regulations define ''major stationary source'' for NNSR in terms of a lower rate dependent on the pollutant and degree of nonattainment in the area. For purposes of the $PM_{2.5}$NAAQS, in addition to the general threshold level of 100 tpy in Moderate $PM_{2.5}$ nonattainment areas, a lower major source threshold of 70 tpy applies in Serious $PM_{2.5}$ nonattainment areas pursuant to subpart 4 of part D, title I of the CAA. *See* 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*vii*) and (*viii*); 40 CFR part 51, appendix S, II.A.4(i)(a)(7) and (8).

Under the NNSR program, direct $PM_{2.5}$ emissions and emissions of each $PM_{2.5}$ precursor are considered separately in accordance with the applicable major source threshold. For example, the threshold for Serious $PM_{2.5}$ nonattainment areas is 70 tpy of direct $PM_{2.5}$, as well as for the $PM_{2.5}$ precursors SO_2, NO_X, VOC, and ammonia.[228] See 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*vii*) and (*viii*); 40 CFR part 51, appendix S, II.A.4.(i)(a)(7) and (8). A source qualifies as major for nonattainment NSR in a $PM_{2.5}$ nonattainment area if it emits or has the potential to emit direct $PM_{2.5}$ or any $PM_{2.5}$ precursor in an amount equal to or greater than the applicable threshold.

For modifications, NNSR applies to proposed physical changes or changes in the method of operation of an existing stationary source where (1) the source is major for the nonattainment pollutant (or a precursor for that pollutant) and (2) the physical change or change in the method of operation of a major stationary source results, first, in a significant emissions increase of a regulated NSR pollutant and, second, in a significant net emissions increase of that same nonattainment pollutant (or same precursor for that pollutant). *See* 40 CFR 51.165(a)(1)(v)(A); 40 CFR part 51, appendix S, II.A.5.(i). For example, to qualify as a major modification for SO_2 (as a $PM_{2.5}$ precursor) in a Moderate $PM_{2.5}$ nonattainment area, the existing source would have to have the potential to emit 100 tpy or more of SO_2, and the project would have to result in an increase in SO_2 emissions of 40 tpy or more. See 40 CFR 51.165(a)(1)(x)(A).

New major stationary sources and major modifications for $PM_{2.5}$ subject to NNSR must comply with the ''lowest achievable emission rate'' (LAER), as defined in the CAA and NNSR rules. Such sources must also perform other analyses and obtain emission offsets, as required under section 173 of the CAA and applicable regulations.

Following the promulgation of this revised primary annual $PM_{2.5}$ NAAQS, some new areas may be designated nonattainment for $PM_{2.5}$. Where a State does not have an existing NNSR program or where the current NNSR program does not apply to $PM_{2.5}$, that State will be required to submit the necessary SIP revisions to ensure that new major stationary sources and major modifications for $PM_{2.5}$ or a $PM_{2.5}$ precursor undergo preconstruction review pursuant to the NNSR program. States with designated nonattainment areas for the revised primary annual $PM_{2.5}$ NAAQS are required to make SIP submissions to meet nonattainment plan requirements within 18 months from the effective date of designations, as required under CAA section 189(a)(2)(B). States that have existing NNSR program requirements that cannot be interpreted to apply at the time of designation to the revised primary annual $PM_{2.5}$ NAAQS may, in the interim, issue permits in accordance with the applicable nonattainment permitting requirements contained in 40 CFR part 51, appendix S, which would apply to the revised primary annual $PM_{2.5}$ NAAQS upon its effective date. *See* 73 FR 28321, 28340, May 16, 2008.

Finally, the EPA has released several documents that discuss air permitting

[226] 40 CFR 51.166(k) states that SIPs must require that the owner or operator of the proposed source or modification demonstrate that allowable emission increases from the proposed source or modification, in conjunction with all other applicable emissions increases or reductions (including secondary emissions), would not cause or contribute to air pollution in violation of: (i) Any national ambient air quality standard in any air quality control region; or (ii) any applicable maximum allowable increase over the baseline concentration in any area.

[227] *See, e.g.,* Memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards to Regional Air Division Directors, Guidance Concerning Implementation of the 1-hour SO_2 NAAQS for the Prevention of Significant Deterioration Program. August 23, 2010. Office of Air Quality Planning and Standards U.S. EPA, Research Triangle Park. Available at: *https://www.epa.gov/sites/default/files/2015-07/documents/appwso2.pdf;* 44 FR 3274, 3278, January 16, 1979; See also *In re Interpower of New York, Inc.,* 5 E.A.D. 130, 141 (EAB 1994) (describing an EPA Region 2 PSD permit that relied in part on offsets to demonstrate the source would not cause or contribute to a violation of the NAAQS). 52 FR 24634, 24684, July 1, 1987; 78 FR 3085, 3261–62, January 15, 2013. The EPA has recognized the ability of sources to obtain offsets in the context of PSD though the PSD provisions of the Act do not expressly reference offsets as the NNSR provisions of the Act do. *See* 80 FR 65292, 65441, October 26, 2015.

[228] All of these pollutants are identified as precursors to $PM_{2.5}$ in NNSR regulations. *See* 40 CFR 51.165(a)(1)(xxxvii)(C)(*2*). No significant emission rate is established by the EPA for ammonia, and states are required to define ''significant'' for ammonia for their respective areas unless the state pursues the optional precursor demonstration to exclude ammonia from planning requirements. *See* 40 CFR 51.165(a)(1)(x)(F); 40 CFR 51.165(a)(13).

and environmental justice, including, for example, a memorandum [229] and attached permitting principles.[230] The EPA recommends that PSD and NNSR permitting authorities review this memorandum and the principles and consider applying them in their air permitting actions as appropriate to help identify, analyze, and address environmental justice concerns in those air permitting actions to help ensure that the NAAQS achieve their intended health benefits for at-risk populations.

F. Transportation Conformity Program

Transportation conformity is required under CAA section 176(c) to ensure that transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects will not cause or contribute to any new air quality violation, increase the frequency or severity of any existing violation, or delay timely attainment or any required interim emissions reductions or other milestones. Transportation conformity applies to areas that are designated as nonattainment or nonattainment areas that have been redesignated to attainment with an approved CAA section 175A maintenance plan (*i.e.,* maintenance areas) for transportation-related criteria pollutants: carbon monoxide, ozone, NO_2, $PM_{2.5}$, and PM_{10}. Transportation conformity for the revised primary annual $PM_{2.5}$ NAAQS does not apply until one year after the effective date of nonattainment designations for that NAAQS. *See* CAA section 176(c)(6) and 40 CFR 93.102(d)). The EPA's Transportation Conformity Rule [231] establishes the criteria and procedures for determining whether transportation activities conform to the SIP. No changes are being made to the transportation conformity rule in this final rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. However, in the future, the EPA intends to review the need to issue or revise guidance describing how the current conformity rule applies in nonattainment and maintenance areas for the revised primary annual $PM_{2.5}$ NAAQS, as needed.

G. General Conformity Program

The conformity requirement under CAA section 176(c) ensures that federal activities implemented by federal agencies will not interfere with a State's ability to attain and maintain the NAAQS. Under CAA 176(c)(1), the requirement prohibits Federal agencies from approving, permitting, licensing, or funding activities that do not conform to the purpose of the applicable SIP for the control and prevention of air pollution. *See* CAA 176(c)(1)(A). Under CAA 176(c)(1)(B), conformity to an implementation plan means that federal activities will not cause or contribute to any new violations of the NAAQS, increase the frequency or severity of any existing NAAQS violation, or delay timely attainment or any required interim emissions reductions or other milestones contained in the applicable SIP.

The general conformity program [232] implements CAA section 176(c)(4)(A), and the criteria and procedures for determining conformity of federal activities to the applicable SIP are established under 40 CFR part 93 subpart B, sections 93.150 through 93.165. General Conformity applies to federal activities that (1) would cause emissions of relevant criteria or precursor pollutants to originate within nonattainment areas or areas that have been redesignated to attainment with an approved CAA section 175A maintenance plan (*i.e.,* maintenance areas), as set forth under 40 CFR 93.153, and (2) are not Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) transportation projects as defined in 40 CFR 93.101 under the transportation conformity requirements. *See* 40 CFR 93.153. General conformity for the revised primary annual $PM_{2.5}$ NAAQS does not apply until one year after the effective date of the nonattainment designation for that NAAQS. *See* 40 CFR 93.153(k).

With regard to issues regarding prescribed fires, which were addressed earlier in this action, here is some additional information regarding prescribed fires and General Conformity regulations. Under the General Conformity regulations at 40 CFR 93.153(c)(4), a conformity evaluation is not required to support a decision by a federal agency to conduct or carry out prescribed burning when the burn is consistent with the terms of a land management plan or other plan that includes the prescribed burn at issue, where the overall plan that includes the burn was previously evaluated under 40 CFR part 93 subpart B by the responsible federal agency, and the agency found the plan conforms under CAA paragraphs 176(c)(1)(A) and (1)(B). This assumes the burn at issue will be conducted by meeting any conditions specified as necessary for meeting conformity in the agency's decision to approve the plan. Alternatively, a presumption of conformity applies also under 40 CFR 93.153(i)(2) for prescribed fires conducted in accordance with a Smoke Management Program that meets the requirements of the EPA's 1998 Interim Air Quality Policy on Wildland and Prescribed Fires or an equivalent replacement EPA policy. The preamble to the Exceptional Events Rule explains that the EPA adapted language associated with the six basic components of a certifiable Smoke Management Program for exceptional events purposes from the 1998 Interim Air Quality Policy on Wildland and Prescribed Fires (*see, e.g.,* 81 FR 68216, 68252 (including footnote 75), 68256, October 2, 2016). The Exceptional Events Rule at 40 CFR 50.14(a)(3)(ii)(A) also indicates that certain requirements within the Exceptional Events Rule can be satisfied if a prescribed fire is conducted under a certified Smoke Management Program or using appropriate basic smoke management practices such as those identified in Table 1 to 40 CFR 50.14 (*see e.g.,* 81 FR 68216, 68250–68257, 68277–68278, October 3, 2016).

No changes are being made to the general conformity regulations in this final rulemaking and the EPA notes that the courts recognize the regulations constitute control for the established $PM_{2.5}$ and PM_{10} NAAQS. However, in the future, the EPA intends to review the need to issue or revise guidance describing how the current General Conformity regulations apply within nonattainment and maintenance areas for the revised primary annual $PM_{2.5}$ NAAQS, as needed.[233]

IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be

[229] Memorandum from Joseph Goffman, Principal Deputy Assistant Administrator, Office of Air and Radiation, to Air and Radiation Division Directors, ''Principles for Addressing Environmental Justice in Air Permitting'' (December 22, 2022), available at *https://www.epa.gov/caa-permitting/ej-air-permitting-principles-addressing-environmental-justice-concerns-air.*

[230] *Id.,* Attachment, ''EJ in Air Permitting: Principles for Addressing Environmental Justice Concerns in Air Permitting'' (December 2022), available at *https://www.epa.gov/caa-permitting/ej-air-permitting-principles-addressing-environmental-justice-concerns-air.*

[231] 40 CFR part 93, subpart A.

[232] 40 CFR part 93 subpart B.

[233] Further, the EPA's current Unified Agenda and Regulatory Plan includes its intention to issue a proposed rule to amend the General Conformity Regulations. The EPA intends to address in that regulatory action topics regarding prescribed fire, including consideration of smoke management approaches such as those discussed in the Exceptional Events Rule, among other topics. See, *e.g., https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2060-AV28.*

found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is ''significant regulatory action'' as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an illustrative analysis of the potential costs and benefits associated with this action. This analysis, ''Regulatory Impact Analysis for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter,'' is available in the Regulatory Impact Analysis (RIA) docket (EPA–HQ–OAR–2019–0587) and briefly summarized below. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

The RIA estimates the costs and monetized human health benefits in 2032, after implementing existing and expected regulations and assessing emissions reductions to meet the current primary annual and 24-hour particulate matter NAAQS (12/35 μg/m^3), associated with applying national control strategies for the revised annual and 24-hour standard levels of 9/35 μg/m^3, as well as the following less and more stringent alternative standard levels: (1) A less stringent alternative annual standard level of 10 μg/m^3 in combination with the current 24-hour standard (*i.e.,* 10/35 μg/m^3), (2) a more stringent alternative annual standard level of 8 μg/m^3 in combination with the current 24-hour standard (*i.e.,* 8/35 μg/m^3), and (3) a more stringent alternative 24-hour standard level of 30 μg/m^3 in combination with an annual standard level of 10 μg/m^3 (*i.e.,* 10/30 μg/m^3). Table 3 provides a summary of the estimated monetized benefits, costs, and net benefits associated with applying national control strategies toward reaching the revised and alternative standard levels.

TABLE 3—ESTIMATED MONETIZED BENEFITS, COSTS, AND NET BENEFITS OF THE ILLUSTRATIVE CONTROL STRATEGIES APPLIED TOWARD THE PRIMARY REVISED AND ALTERNATIVE ANNUAL AND DAILY STANDARD LEVELS OF 10/35 μg/m^3, 10/30 μg/m^3, 9/35 μg/m^3, AND 8/35 μg/m^3 IN 2032 FOR THE U.S.

[Millions of 2017$]

	10/35	10/30	9/35	8/35
Benefits[a]	$8,500 and $17,000	$10,000 and $21,000	$22,000 and $46,000	$48,000 and $99,000.
Costs[b]	$200	$340	$590	$1,500.
Net Benefits	$8,300 and $17,000	$9,900 and $21,000	$22,000 and $46,000	$46,000 and $97,000.

Notes: Rows may not appear to add correctly due to rounding. We provide a snapshot of costs and benefits in 2032, using the best available information to approximate social costs and social benefits recognizing uncertainties and limitations in those estimates. The estimated costs and monetized human health benefits associated with applying national control strategies do not fully account for all the emissions reductions needed to reach the final and more stringent alternative standard levels for some standard levels analyzed.

[a] We assume that there is a cessation lag between the change in PM exposures and the total realization of changes in mortality effects. Specifically, we assume that some of the incidences of premature mortality related to $PM_{2.5}$ exposures occur in a distributed fashion over the 20 years following exposure, which affects the valuation of mortality benefits at different discount rates. Similarly, we assume there is a cessation lag between the change in PM exposures and both the development and diagnosis of lung cancer. The benefits are associated with two point estimates from two different epidemiologic studies, and we present the benefits calculated at a real discount rate of 3 percent. The monetized benefits exclude additional health and welfare benefits that could not be quantified.

[b] The costs are annualized using a 7 percent interest rate.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060–0084. The data collected through this information collection consist of ambient air concentration measurements for the seven air pollutants with national ambient air quality standards (*i.e.,* ozone, sulfur dioxide, nitrogen dioxide, lead, carbon monoxide, $PM_{2.5}$ and PM_{10}), ozone precursors, air toxics, meteorological variables at a select number of sites, and other supporting measurements. Accompanying the pollutant concentration data are quality assurance/quality control data and air monitoring network design information. The EPA and others (*e.g.,* State and local air quality management agencies, tribal entities, environmental organizations, academic institutions, industrial groups) use the ambient air quality data for many purposes including informing the public and other interested parties of an area's air quality, judging an area's air quality in comparison with the established health or welfare standards, evaluating an air quality management agency's progress in achieving or maintaining air pollutant levels below the national and local standards, developing and revising State Implementation Plans (SIPs), evaluating air pollutant control strategies, developing or revising national control policies, providing data for air quality model development and validation, supporting enforcement actions, documenting episodes and initiating episode controls, assessing air quality trends, and conducting air pollution research.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this final rule establishes national standards for allowable concentrations of PM in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), rev'd in part on other grounds, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Furthermore, as indicated previously, in setting a NAAQS the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. See also *American Trucking Associations* v. *EPA,* 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of the RIA pursuant to the Unfunded Mandates Reform Act would not furnish any information that the court could consider in reviewing the NAAQS).

E. Executive Order 13132: Federalism

This action will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. However, the EPA recognizes that States will have a substantial interest in this action and any future revisions to associated requirements.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes as Tribes are not obligated to adopt or implement any NAAQS. In addition, Tribes are not obligated to conduct ambient monitoring for PM or to adopt the ambient monitoring requirements of 40 CFR part 58. Thus, Executive Order 13175 does not apply to this action. However, consistent with the *EPA Policy on Consultation and Coordination with Indian Tribes,* the EPA offered consultation to all 574 Federally Recognized Tribes during the development of this action. Although no Tribes requested consultation, the EPA provided informational meetings including an informational meeting with the Pueblo de San Ildefonso and provided information on the monthly National Tribal Air Association calls.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to Executive Order 13045 because it is a significant regulatory action under section 3(f)(1) of Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of PM exposures on children. The protection offered by these standards may be especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as a susceptible population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. Children make up a substantial fraction of the U.S. population, and often have unique factors that contribute to their increased risk of experiencing a health effect due to exposures to ambient air pollutants because of their continuous growth and development. As described in the 2019 Integrated Science Assessment, children may be particularly at risk for health effects related to ambient air $PM_{2.5}$ exposures compared with adults because they have (1) a developing respiratory system, (2) increased ventilation rates relative to body mass compared with adults, and (3) an increased proportion of oral breathing, particularly in boys, relative to adults. More detailed information on the evaluation of the scientific evidence and policy considerations pertaining to children, including an explanation for why the Administrator judges the revised standards to be requisite to protect public health, including the health of children, with an adequate margin of safety, are contained in section II.A.2. ''Overview of the Health Effects Evidence'', section II.A.2.b ''Public Health Implications and At-Risk Populations'' and II.B ''Conclusions on the Primary $PM_{2.5}$ Standards'' of this preamble. Copies of all documents have been placed in the public docket for this action. The Administrator judges that revising the primary annual $PM_{2.5}$ standard to a level of 9.0 $\mu g/m^3$ and retaining the primary 24-hour $PM_{2.5}$ standard provides requisite public health protection with an adequate margin of safety, including for children. Furthermore, the Policy on Children's Health also applies to this action. Information on how the Policy was applied is described in section II.A.2 ''Overview of the Health Effects Evidence'', section II.A.2.b ''Public Health Implications and At-Risk Populations'' and II.B ''Conclusions on the Primary $PM_{2.5}$ Standards'' of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this action is to revise level of the primary annual $PM_{2.5}$ NAAQS. The action does not prescribe specific pollution control strategies by which these ambient standards and monitoring revisions will be met. Such strategies will be developed by States on a case-by-case basis, and the EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, the EPA concludes that this action does not constitute a significant energy action as defined in Executive Order 13211.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking involved environmental monitoring or measurement. The EPA has decided it will continue to use the existing indicators for fine ($PM_{2.5}$) and coarse (PM_{10}) particles. The indicator for fine particles is measured using the Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere (appendix L to 40 CFR part 50), which is known as the $PM_{2.5}$ FRM, and the indicator for coarse particles is measured using the Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere (appendix J to 40 CFR part 50), which is known as the PM_{10} FRM.

To the extent feasible, the EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner.

It is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not practically possible to fully define the FRM in performance terms to account for this variability. Nevertheless, our approach in the past has resulted in multiple brands of monitors being approved as FRM for PM, and we expect this to continue. Also, the FRMs described in 40 CFR part 50 and the equivalency criteria described in 40 CFR part 53, constitute a performance-based measurement system for PM, since methods that meet the field testing and performance criteria can be approved as FEMs. Since finalized in 2006 (71 FR 61236, October 17, 2006) the new field and performance criteria for approval of $PM_{2.5}$ continuous FEMs has resulted in the approval of 13 approved FEMs. In summary, for measurement of $PM_{2.5}$ and PM_{10}, the EPA relies on both FRMs and FEMs, with FEMs relying on a PBMS approach for their approval. The EPA is not precluding the use of any other method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions associated with the primary $PM_{2.5}$ NAAQS that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns. There is strong evidence for racial and ethnic disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk, as assessed in the 2019 Integrated Science Assessment and with even more evidence available since the literature cutoff date for the 2019 Integrated Science Assessment and evaluated in the Supplement to the 2019 Integrated Science Assessment. There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations. Black populations or individuals that live in predominantly Black neighborhoods experience higher $PM_{2.5}$ exposures, in comparison to non-Hispanic White populations. There is also consistent evidence across multiple studies that demonstrate increased risk of $PM_{2.5}$-related health effects, with the strongest evidence for health risk disparities for mortality. There is also evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations for cause-specific mortality and incident hypertension.

Socioeconomic status (SES) is a composite measure that includes metrics such as income, occupation, or education, and can play a role in access to healthy environments as well as access to healthcare. SES may be a factor that contributes to differential risk from $PM_{2.5}$-related health effects. Studies assessed in the 2019 Integrated Science Assessment and Supplement to the 2019 Integrated Science Assessment provide evidence that lower SES communities are exposed to higher concentrations of $PM_{2.5}$ compared to higher SES communities. Studies using composite measures of neighborhood SES consistently demonstrated a disparity in both $PM_{2.5}$ exposure and the risk of $PM_{2.5}$-related health outcomes. There is some evidence that supports associations larger in magnitude between mortality and long-term $PM_{2.5}$ exposures for those with low income or living in lower income areas compared to those with higher income or living in higher income neighborhoods. Additionally, evidence supports conclusions that lower SES is associated with cause-specific mortality and certain health endpoints (*i.e.,* HI and CHF), but less so for all-cause or total (non-accidental) mortality.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with environmental justice concerns.

The EPA additionally identified and addressed environmental justice concerns by providing opportunities for public input on the proposed decisions. The EPA held a multi-day virtual public hearing for the public to provide oral testimony and there was a 60-day public comment period for the proposed action. As described in section II.A.3 above, the EPA conducted a risk assessment to support this action that included an at-risk analysis that evaluates exposure and $PM_{2.5}$ mortality risk for older adults (*e.g.,* 65 years and older), stratified for White, Black, Asian, Native American, Non-Hispanic, and Hispanic individuals. This at-risk analysis found that compared to a primary annual $PM_{2.5}$ standard with a level of 12.0 μg/m^3, meeting a revised annual standard with a level of 9.0 μg/m^3 is estimated to reduce $PM_{2.5}$-associated health risks in the 30 study areas controlled by the annual standard by about 22–28% and is expected to reduce disparities in exposure and risk among these populations.

The information supporting this Executive Order review is is contained in sections II.A.2, II.B.3.a, II.B.3.c, II.B.2, and II.B.4. of this preamble and also in the 2019 Integrated Science Assessment, Supplement to the 2019 Integrated Science Assessment, and 2022 Policy Assessment. The EPA has carefully evaluated the potential impacts on minority populations and low SES populations as discussed in sections II.A.2, II.A.3, II.B.2, and II.B.4 of this preamble. The 2019 Integrated Science Assessment, Supplement to the Integrated Science Assessment, and 2022 Policy Assessment contain the evaluation of the scientific evidence, quantitative risk analyses and policy considerations that pertain to these populations. These documents are available in the public docket for this action.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Add § 50.20 to read as follows:

§ 50.20 National primary ambient air quality standards for $PM_{2.5}$.

(a) The national primary ambient air quality standards for $PM_{2.5}$ are 9.0 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration and 35 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(1) A reference method based on appendix L to this part and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The primary annual $PM_{2.5}$ standard is met when the annual arithmetic mean concentration, as determined in accordance with appendix N to this part, is less than or equal to 9.0 $\mu g/m^3$.

(c) The primary 24-hour $PM_{2.5}$ standard is met when the 98th percentile 24-hour concentration, as determined in accordance with appendix N to this part, is less than or equal to 35 $\mu g/m^3$.

■ 3. Amend appendix K to part 50 by:

■ a. In section 1.0 revising paragraph (b);

■ b. In section 2.3 adding paragraph (d); and

■ c. In section 3.0 adding paragraphs (a) and (b).

The revision and additions read as follows:

Appendix K to Part 50—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 General

* * * * *

(b) The terms used in this appendix are defined as follows:

Average refers to the arithmetic mean of the estimated number of exceedances per year, as per section 3.1 of this appendix.

Collocated monitors refer to two or more air measurement instruments for the same parameter (*e.g.,* PM_{10} mass) operated at the same site location, and whose placement is consistent with part 53 of this chapter. For purposes of considering a combined site record in this appendix, when two or more monitors are operated at the same site, one

monitor is designated as the ''primary'' monitor with any additional monitors designated as ''collocated.'' It is implicit in these appendix procedures that the primary monitor and collocated monitor(s) are all reference or equivalent methods; however, it is not a requirement that the primary and collocated monitors utilize the same specific sampling and analysis method.

Combined site data record is the data set used for performing computations in this appendix and represents data for the primary monitors augmented with data from collocated monitors according to the procedure specified in section 3.0(a) of this appendix.

Daily value for PM_{10} refers to the 24-hour average concentration of PM_{10} calculated or measured from midnight to midnight (local time).

Exceedance means a daily value that is above the level of the 24-hour standard after rounding to the nearest 10 $\mu g/m^3$ (*i.e.,* values ending in 5 or greater are to be rounded up).

Expected annual value is the number approached when the annual values from an increasing number of years are averaged, in the absence of long-term trends in emissions or meteorological conditions.

Primary monitors are suitable monitors designated by a State or local agency in their annual network plan as the default data source for creating a combined site data record. If there is only one suitable monitor at a particular site location, then it is presumed to be a primary monitor.

Year refers to a calendar year.

* * * * *

2.3 Data Requirements

* * * * *

(d) 24-hour average concentrations will be computed from submitted hourly PM_{10} concentration data for each corresponding day of the year and the result will be stored in the first, or start, hour (*i.e.,* midnight, hour '0') of the 24-hour period. A 24-hour average concentration shall be considered valid if at least 75 percent of the hourly averages (*i.e.,* 18 hourly values) for the 24-hour period are available. In the event that fewer than all 24 hourly average concentrations are available (*i.e.,* fewer than 24 but at least 18), the 24-hour average concentration shall be computed on the basis of the hours available using the number of available hours within the 24-hour period as the divisor (*e.g.,* the divisor is 19 if 19 hourly values are available). 24-hour periods with 7 or more missing hours shall also be considered for computations in this appendix if, after substituting zero for all missing hourly concentrations, the resulting 24-hour average daily value exceeds the level of the 24-hour standard specified in § 50.6 after rounding to the nearest 10 $\mu g/m^3$.

* * * * *

3.0 Computational Equations for the 24-Hour Standards

(a) All computations shown in this appendix shall be implemented on a site-level basis. Site level concentration data shall be processed as follows:

(1) The default dataset for PM_{10} mass concentrations for a site shall consist of the measured concentrations recorded from the designated primary monitor(s). All daily values produced by the primary monitor are considered part of the site record.

(2) If a daily value is not produced by the primary monitor for a particular day, but a value is available from a single collocated monitor, then that collocated monitor value shall be considered part of the combined site data record. If daily value data is available from two or more collocated monitors, the average of those collocated values shall be used as the daily value. The data record resulting from this procedure is referred to as the ''combined site data record.''

(b) In certain circumstances, including but not limited to site closures or relocations, data from two nearby sites may be combined into a single site data record for the purpose of calculating a valid design value. The appropriate Regional Administrator may approve such combinations if the Regional Administrator determines that the measured concentrations do not differ substantially between the two sites, taking into consideration factors such as distance between sites, spatial and temporal patterns in air quality, local emissions and meteorology, jurisdictional boundaries, and terrain features.

* * * * *

■ 4. Amend appendix L to part 50 by revising section 7.3.4 and adding section 7.3.4.5 to read as follows:

Appendix L to Part 50—Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere

* * * * *

7.3.4 *Particle size separator.* The sampler shall be configured with one of the three alternative particle size separators described in this section. One separator is an impactor-type separator (WINS impactor) described in sections 7.3.4.1, 7.3.4.2, and 7.3.4.3 of this appendix. One alternative separator is a cyclone-type separator (VSCC™) described in section 7.3.4.4 of this appendix. The other alternative separator is also a cyclone-type separator (TE–$PM_{2.5}$C) described in section 7.3.4.5 of this appendix.

* * * * *

7.3.4.5 A second cyclone-type separator is identified as a Tisch TE–$PM_{2.5}$C Cyclone particle size separator specified as part of EPA-designated reference method RFPS–1014–219 and as manufactured by Tisch Environmental Incorporated, 145 S. Miami Avenue, Village of Cleves, Ohio 45002.

* * * * *

■ 5. Amend appendix N to part 50 by:
■ a. In section 1.0 revising paragraph (a);
■ b. In section 3.0 adding paragraph (d)(3);
■ c. In section 4.1 revising paragraph (a); and
■ d. In section 4.2 revising paragraph (a).

The addition and revisions read as follows.

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

1.0 General

(a) This appendix explains the data handling conventions and computations necessary for determining when the national ambient air quality standards (NAAQS) for $PM_{2.5}$ are met, specifically the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in §§ 50.7, 50.13, 50.18, and 50.20. $PM_{2.5}$ is defined, in general terms, as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. $PM_{2.5}$ mass concentrations are measured in the ambient air by a Federal Reference Method (FRM) based on appendix L to this part, as applicable, and designated in accordance with part 53 of this chapter or by a Federal Equivalent Method (FEM) designated in accordance with part 53 of this chapter. Only those FRM and FEM measurements that are derived in accordance with part 58 of this chapter (*i.e.,* that are deemed ''suitable'') shall be used in comparisons with the $PM_{2.5}$ NAAQS. The data handling and computation procedures to be used to construct annual and 24-hour NAAQS metrics from reported $PM_{2.5}$ mass concentrations, and the associated instructions for comparing these calculated metrics to the levels of the $PM_{2.5}$ NAAQS, are specified in sections 2.0, 3.0, and 4.0 of this appendix.

* * * * *

3.0 Requirements for Data Use and Data Reporting for Comparisons With the NAAQS for $PM_{2.5}$

* * * * *

(d) * * *

(3) In certain circumstances, including but not limited to site closures or relocations, data from two nearby sites may be combined into a single site data record for the purpose of calculating a valid design value. The appropriate Regional Administrator may approve such site combinations if the Regional Administrator determines that the measured concentrations do not differ substantially between the two sites, taking into consideration factors such as distance between sites, spatial and temporal patterns in air quality, local emissions and meteorology, jurisdictional boundaries, and terrain features.

* * * * *

4.1 Annual $PM_{2.5}$ NAAQS

(a) Levels of the primary and secondary annual $PM_{2.5}$ NAAQS are specified in §§ 50.7, 50.13, 50.18, and 50.20 as applicable.

* * * * *

4.2 Twenty-Four-Hour $PM_{2.5}$ NAAQS

(a) Levels of the primary and secondary 24-hour $PM_{2.5}$ NAAQS are specified in §§ 50.7, 50.13, 50.18, and 50.20 as applicable.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 6. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart A—General Provisions

■ 7. Amend § 53.4 by:
■ a. Revising paragraph (a);
■ b. Adding paragraph (b)(7); and
■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for FRM or FEM determinations and modification requests of existing designated instruments shall be submitted to: U.S. Environmental Protection Agency, Director, Center for Environmental Measurement and Modeling, Reference and Equivalent Methods Designation Program (MD–D205–03), 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711 (commercial delivery address: 4930 Old Page Road, Durham, North Carolina 27703).

* * * * *

(b) * * *

(7) All written materials for new FRM and FEM applications and modification requests must be submitted in English in MS Word format. For any calibration certificates originally written in a non-English language, the original non-English version of the certificate must be submitted to EPA along with a version of the certificate translated to English. All laboratory and field data associated with new FRM and FEM applications and modification requests must be submitted in MS Excel format. All worksheets in MS Excel must be unprotected to enable full inspection as part of the application review process.

* * * * *

(d) For candidate reference or equivalent methods or for designated instruments that are the subject of a modification request, the applicant, if requested by EPA, shall provide to EPA a representative sampler or analyzer for test purposes. The sampler or analyzer shall be shipped free on board (FOB) destination to Director, Center for Environmental Measurements and Modeling, Reference and Equivalent Methods Designation Program (MD D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrently with or within 30 days of the arrival of the other application materials. This sampler or analyzer may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph (d) malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded the opportunity to repair or replace the device at no cost to the EPA. Upon completion of EPA testing, the sampler or analyzer submitted under this paragraph (d) shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the sampler or analyzer upon return to the applicant.

■ 8. Amend § 53.8 by revising paragraph (a) to read as follows:

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as an FRM or FEM (as applicable) by and upon publication of the designation in the **Federal Register**. Applicants shall not publicly announce, market, or sell the candidate sampler and analyzer as an approved FRM or FEM (as applicable) until the designation is published in the **Federal Register**.

* * * * *

■ 9. Amend § 53.14 by revising paragraphs (c)(4), (5), and (6) to read as follows:

§ 53.14 Modification of a reference or equivalent method.

* * * * *

(c) * * *

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 90-day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify which tests are necessary and how they shall be interpreted (in such cases, the 90-day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 90-day period shall commence 1 calendar day after the additional tests are completed).

* * * * *

■ 10. Revise table A–1 to subpart A of part 53 to read as follows:

TABLE A–1 TO SUBPART A OF PART 53—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS

Pollutant	Reference or equivalent	Manual or automated	Applicable appendix of part 50 of this chapter	Applicable subparts of this part					
				A	B	C	D	E	F
SO_2	Reference	Manual	A–2						
		Automated	A–1	✓	✓				
	Equivalent	Manual	A–1	✓		✓			
		Automated	A–1	✓	✓	✓			
CO	Reference	Automated	C	✓	✓				
	Equivalent	Manual	C	✓		✓			
		Automated	C	✓	✓	✓			
O_3	Reference	Automated	D	✓	✓				
	Equivalent	Manual	D	✓		✓			
		Automated	D	✓	✓	✓			
NO_2	Reference	Automated	F	✓	✓				
	Equivalent	Manual	F	✓		✓			
		Automated	F	✓	✓	✓			

TABLE A–1 TO SUBPART A OF PART 53—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS—Continued

Pollutant	Reference or equivalent	Manual or automated	Applicable appendix of part 50 of this chapter	Applicable subparts of this part					
				A	B	C	D	E	F
Pb	Reference	Manual	G						
	Equivalent	Manual	G	✓		✓			
		Automated	G	✓		✓			
PM_{10}-Pb	Reference	Manual	Q						
	Equivalent	Manual	Q	✓		✓			
		Automated	Q	✓		✓			
PM_{10}	Reference	Manual	J	✓			✓		
	Equivalent	Manual	J	✓		✓	✓		
		Automated	J	✓		✓	✓		
$PM_{2.5}$	Reference	Manual	L	✓				✓	
	Equivalent Class I	Manual	L	✓		✓		✓	
	Equivalent Class II	Manual	L [1]	✓		[2]✓		✓	[1 2]✓
	Equivalent Class III	Automated	L [1]	✓		✓		✓	[1]✓
$PM_{10-2.5}$	Reference	Manual	L,[2] O	✓				✓	
	Equivalent Class I	Manual	L,[2] O	✓		✓		✓	
	Equivalent Class II	Manual	L,[2] O	✓		[2]✓		✓	[1,2]✓
	Equivalent Class III	Automated	[1] L, [1 2] O	✓		✓		✓	[1]✓

[1] Some requirements may apply, based on the nature of each particular candidate method, as determined by the Administrator.
[2] Alternative Class III requirements may be substituted.

Subpart B—Procedures for Testing Performance Characteristics of Automated Methods for SO_2, CO, O_3, and NO_2

■ 11. Amend table B–1 to subpart B of part 53 by revising footnote 4 to read as follows:

Table B–1 to Subpart B of Part 53—Performance Limit Specifications for Automated Methods

* * * * *

[4] For nitric oxide interference for the SO_2 ultraviolet fluorescence (UVF) method, interference equivalent is ±0.003 ppm for the lower range.

* * * * *

■ 12. Revise table B–3 to subpart B of part 53 to read as follows:

TABLE B–3 TO SUBPART B OF PART 53—INTERFERENT TEST CONCENTRATION [1]

[Parts per million]

Pollutant	Analyzer type [2]	Hydrochloric acid	Ammonia	Hydrogen sulfide	Sulfur dioxide	Nitrogen dioxide	Nitric oxide	Carbon dioxide	Ethylene	Ozone	M-xylene	Water vapor	Carbon monoxide	Methane	Ethane	Naphthalene
SO_2	Ultraviolet fluorescence			[5] 0.1	[4] 0.14	0.5	0.5			0.5	0.2	20,000				[6] 0.05
SO_2	Flame photometric			0.01	[4] 0.14			750				[3] 20,000	50			
SO_2	Gas chromatography			0.1	[4] 0.14			750				[3] 20,000	50			
SO_2	Spectrophotometric-wet chemical (pararosanaline)	0.2	0.1	0.1	[4] 0.14	0.5		750		0.5						
SO_2	Electrochemical	0.2	0.1	0.1	[4] 0.14	0.5	0.5		0.2	0.5		[3] 20,000				
SO_2	Conductivity	0.2	0.1		[4] 0.14	0.5		750								
SO_2	Spectrophotometric-gas phase, including DOAS				[4] 0.14	0.5	0.5			0.5	0.2					
O_3	Ethylene Chemiluminescence			[3] 0.1				750		[4] 0.08		[3] 20,000				
O_3	NO-chemiluminescence			[3] 0.1		0.5		750		[4] 0.08		[3] 20,000				
O_3	Electrochemical		[3] 0.1		0.5	0.5				[4] 0.08		[3] 20,000				
O_3	Spectrophotometric-wet chemical (potassium iodide)		[3] 0.1		0.5	0.5	[3] 0.5			[4] 0.08						
O_3	Spectrophotometric-gas phase, including ultraviolet absorption and DOAS.				0.5	0.5	[3] 0.5			[4] 0.08	0.02	20,000				
CO	Non-dispersive Infrared							750				20,000	[4] 10			
CO	Gas chromatography with flame ionization detector											20,000	[4] 10		0.5	
CO	Electrochemical						0.5		0.2			20,000	[4] 10			
CO	Catalytic combustion-thermal detection		0.1					750	0.2			20,000	[4] 10	5.0	0.5	
CO	IR fluorescence							750				20,000	[4] 10		0.5	
CO	Mercury replacement-UV photometric								0.2				[4] 10		0.5	
NO_2	Chemiluminescent		[3] 0.1		0.5	[4] 0.1	0.5					20,000				
NO_2	Spectrophotometric-wet chemical (azo-dye reaction)				0.5	[4] 0.1	0.5	750		0.5						
NO_2	Electrochemical	0.2	[3] 0.1		0.5	[4] 0.1	0.5	750		0.5		20,000	50			
NO_2	Spectrophotometric-gas phase		[3] 0.1		0.5	[4] 0.1	0.5			0.5		20,000	50			

[1] Concentrations of interferent listed must be prepared and controlled to ±10 percent of the stated value.
[2] Analyzer types not listed will be considered by the Administrator as special cases.
[3] Do not mix interferent with the pollutant.
[4] Concentration of pollutant used for test. These pollutant concentrations must be prepared to ±10 percent of the stated value.
[5] If candidate method utilizes an elevated-temperature scrubber for removal of aromatic hydrocarbons, perform this interference test.
[6] If naphthalene test concentration cannot be accurately quantified, remove the scrubber, use a test concentration that causes a full-scale response, reattach the scrubber, and evaluate response for interference.

■ 13. Amend appendix A to subpart B of part 53 by revising figures B–3 and B–5 to read as follows:

Appendix A to Subpart B of Part 53—Optional Forms for Reporting Test Results

* * * * *

Figure B–3 to Appendix A to Subpart B of Part 53—Form for Test Data and Calculations for Lower Detectable Limit (LDL) and Interference Equivalent (IE) (see § 53.23(c) and (d))

Analyzer _____
Date _____
Pollutant _____

LDL Interference Test Data

Applicant _____

TEST PARAMETER		READING or CALCULATION	TEST NUMBER														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
LOWER DETECTABLE LIMIT		B_Z															
		B_L															
		$LDL = B_L - B_Z$															
INTER-FERENCE EQUIV-ALENT	1	R_1															
		R_{I1}															
		$IE = R_{I1} - R_1$															
	2	R_2															
		R_{I2}															
		$IE = R_{I2} - R_2$															
	3*	R_3															
		R_{I3}															
		$IE = R_{I3} - R_3$															
	4*	R_4															
		R_{I4}															
		$IE = R_{I4} - R_4$															
	5*	R_5															
		R_{I5}															
		$IE = R_{I5} - R_5$															
	TOTAL*	$\sum_{i=1}^{n} \lvert IE_i \rvert$															

*If required.

* * * * *

Figure B–5 to Appendix A to Subpart B of Part 53—Form for Calculating Zero Drift, Span Drift and Precision (see § 53.23(e))

Analyzer _____
Date _____
Pollutant _____

Calculation of Zero Drift, Span Drift, and Precision

Applicant _____

TEST PARAMETER		CALCULATION	TEST DAY (n)														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
ZERO DRIFT	12 HOUR	$12ZD = C_{max} - C_{min}$															
	24 HOUR	$Z = (L_1 + L_2)/2$															
		$24ZD = Z_n - Z_{n-1}$															
		$24ZD = Z'_n - Z'_{n-1}$															
SPAN DRIFT	24 HOUR	$S_n = \frac{1}{6}\sum_{i=7}^{12} P_i$															
		$SD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$															
		$SD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$															
PREC-ISION	20% URL (P_{20})	P20 = % STANDARD DEVIATION of ($P_1 \ldots P_6$)															
	80% URL (P_{80})	P20 = % STANDARD DEVIATION of ($P_7 \ldots P_{12}$)															

* * * * *

Subpart C—Procedures for Determining Comparability Between Candidate Methods and Reference Methods

■ 14. Amend § 53.35 by revising paragraph (b)(1)(ii)(D) to read as follows:

§ 53.35 Test procedure for Class II and Class III methods for $PM_{2.5}$ and $PM_{10-2.5}$.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(D) Site D shall be in a large city east of the Mississippi River, having characteristically high humidity levels.

* * * * *

■ 15. Revise table C–4 to subpart C of part 53 to read as follows:

TABLE C–4 TO SUBPART C OF PART 53—TEST SPECIFICATIONS FOR PM_{10}, $PM_{2.5}$, AND $PM_{10-2.5}$ CANDIDATE EQUIVALENT METHODS

Specification	PM_{10}	$PM_{2.5}$			$PM_{10-2.5}$	
		Class I	Class II	Class III	Class II	Class III
Acceptable concentration range (R_j), μg/m³.	5–300	3–200	3–200	3–200	3–200	3–200.
Minimum number of test sites.	2	1	2	4	2	4.
Minimum number of candidate method samplers or analyzers per site.	3	3	3[1]	3[1]	3[1]	3.[1]
Number of reference method samplers per site.	3	3	3[1]	3[1]	3[1]	3.[1]
Minimum number of acceptable sample sets per site for PM_{10} methods:						
R_j < 20 μg/m³	3					
R_j > 20 μg/m³	3					
Total	10					
Minimum number of acceptable sample sets per site for $PM_{2.5}$ and $PM_{10-2.5}$ candidate equivalent methods:						
R_j < 15 μg/m³ for 24-hr or R_j < 8 μg/m³ for 48-hr samples..		3	3	3	3	3.
Rj > 15 μg/m³ for 24-hr or R_j > 8 μg/m³ for 48-hr samples.		3	3	3	3	3.
Each season		10	23	23	23	23.
Total, each site.		10	23	23 (46 for two-season sites).	23	23 (46 for two-season sites).
Precision of replicate reference method measurements, P_{Rj} or RP_{Rj}, respectively; RP for Class II or III $PM_{2.5}$ or $PM_{10-2.5}$, maximum.	5 μg/m³ or 7%.	2 μg/m³ or 5%.	10%[2]	10%[2]	10%[2]	10%.[2]
Precision of $PM_{2.5}$ or $PM_{10-2.5}$ candidate method, CP, each site.			10%[2]	15%[2]	15%[2]	15%.[2]
Slope of regression relationship.	1 ±0.10	1 ±0.05	1 ±0.10	1 ±0.10	1 ±0.10	1 ±0.12.
Intercept of regression relationship, μg/m³.	0 ±5	0 ±1	Between: 13.55—(15.05 × slope), but not less than—1.5; and 16.56—(15.05 × slope), but not more than +1.5.	Between: 15.05—(17.32 × slope), but not less than—2.0; and 15.05—(13.20 × slope), but not more than +2.0.	Between: 62.05—(70.5 × slope), but not less than—3.5; and 78.95—(70.5 × slope), but not more than +3.5.	Between: 70.50—(82.93 × slope), but not less than—7.0; and 70.50—(61.16 × slope), but not more than +7.0.
Correlation of reference method and candidate method measurements.	≥ 0.97	≥ 0.97	≥ 0.93—for CCV ≤ 0.4; ≥ 0.85 + 0.2 × CCV—for 0.4 ≤ CCV ≤ 0.5; ≥ 0.95—for CCV ≥ 0.5			

[1] Some missing daily measurement values may be permitted; see test procedure.
[2] Calculated as the root mean square over all measurement sets.

Subpart D—Procedures for Testing Performance Characteristics of Methods for PM_{10}

■ 16. Amend § 53.43 by revising the formula in paragraph (a)(2)(xvi) and the formula in paragraph (c)(2)(iv) to read as follows:

§ 53.43 Test procedures.

(a) * * *

(2) * * *

$$CV_E = \left. \sqrt{\frac{\sum_{i=1}^{n} E^2(i) - \frac{1}{n}\left(\sum_{i=1}^{n} E\,(i)\right)^2}{n-1}} \right/ \bar{E}$$

(xvi) * * *

* * * * *

(c) * * *

(2) * * *

(iv) * * *

$$Pj = \sqrt{\frac{\sum_{i=1}^{3} C^2(i)(j) - \frac{1}{3}\left(\sum_{i=1}^{3} C\,(i)(j)\right)^2}{2}}$$

if $\bar{C}_j$ is below 80 μg/m³, or

$$RP_j = \ 100\%\ x \left. \sqrt{\frac{\sum_{i=1}^{3} C^2(i)\,(j) - \frac{1}{3}\left(\sum_{i=1}^{3} C\,(i)(j)\right)^2}{2}} \right/ \overline{C}_{(j)}$$

if $\bar{C}_j$ is above 80 μg/m³.

Subpart E—Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I and Class II Equivalent Methods for $PM_{2.5}$ or PM_{10}–2.5

■ 17. Amend § 53.51 by revising paragraph (d)(2) to read as follows:

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

* * * * *

(d) * * *

(2) *VSCC and TE–$PM_{2.5}$C separators.* For samplers and monitors utilizing the BGI VSCC or Tisch TE–$PM_{2.5}$C particle size separators specified in sections 7.3.4.4 and 7.3.4.5 of appendix L to part 50 of this chapter, respectively, the respective manufacturers shall identify the critical dimensions and manufacturing tolerances for the separator, devise appropriate test procedures to verify that the critical dimensions and tolerances are maintained during the manufacturing process, and carry out those procedures on each separator manufactured to verify conformance of the manufactured products. The manufacturer shall also maintain records of these tests and their test results and submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance tests.

* * * * *

Subpart F—Procedures for Testing Performance Characteristics of Class II Equivalent Methods for $PM_{2.5}$

■ 18. Amend § 53.61 by revising paragraph (g) introductory text, the first sentence of paragraph (g)(1), the first sentence of (g)(1)(i), (g)(2)(i) and adding paragraph (g)(2)(iii) to read as follows:

§ 53.61 Test conditions.

* * * * *

(g) *Vibrating Orifice Aerosol Generator (VOAG) and Flow-Focusing Monodisperse Aerosol Generator (FMAG) conventions.* This section prescribes conventions regarding the use of the vibrating orifice aerosol generator (VOAG) and the flow-focusing monodisperse aerosol generator (FMAG) for the size-selective performance tests outlined in §§ 53.62, 53.63, 53.64, and 53.65.

(1) *Particle aerodynamic diameter.* The VOAG and FMAG produce near-monodisperse droplets through the controlled breakup of a liquid jet. * * *

(i) The physical diameter of a generated spherical particle can be calculated from the operational parameters of the VOAG and FMAG as:

* * * * *

(2) * * *

(i) Solid particle tests performed in this subpart shall be conducted using particles composed of ammonium fluorescein. For use in the VOAG or FMAG, liquid solutions of known volumetric concentration can be prepared by diluting fluorescein powder ($C_2OH_{12}O_5$, FW = 332.31, CAS 2321–07–5) with aqueous ammonia. Guidelines for preparation of fluorescein solutions of the desired volume concentration (C_{vol}) are presented in Vanderpool and Rubow (1988) (Reference 2 in appendix A to this subpart). For purposes of converting particle physical diameter to aerodynamic diameter, an ammonium fluorescein particle density of 1.35 g/cm³ shall be used.

* * * * *

(iii) Calculation of the physical diameter of the particles produced by the VOAG and FMAG requires

knowledge of the liquid solution's volume concentration (C_{vol}). Because uranine is essentially insoluble in oleic acid, the total particle volume is the sum of the oleic acid volume and the uranine volume. The volume concentration of the liquid solution shall be calculated as:

Equation 5 to Paragraph (g)(2)(iii)

$$C_{vol} = \frac{V_u + V_{oleic}}{V_{sol}} = \frac{(M_u/P_u) + (M_{oleic}/P_{oleic})}{V_{sol}}$$

Where:
V_u = uranine volume, ml;
V_{oleic} = oleic acid volume, ml;
V_{sol} = total solution volume, ml;
M_u = uranine mass, g;
P_u = uranine density, g/cm^3;
M_{oleic} = oleic acid mass, g; and
P_{oleic} = oleic acid density, g/cm^3.
* * * * *

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 19. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

Subpart A—General Provisions

■ 20. Amend § 58.1 by:
■ a. Removing the definition for ''Approved regional method (ARM)''; and
■ b. Revising the definition for ''Traceable.''

The revision reads as follows:

§ 58.1 Definitions.

* * * * *

Traceable means a measurement result from a local standard whereby the result can be related to the International System of Units (SI) through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. Traceable measurement results must be compared and certified, either directly or via not more than one intermediate standard, to a National Institute of Standards and Technology (NIST)-certified reference standard. Examples include but are not limited to NIST Standard Reference Material (SRM), NIST-traceable Reference Material (NTRM), or a NIST-certified Research Gas Mixture (RGM). Traceability to the SI through other National Metrology Institutes (NMIs) in addition to NIST is allowed if a Declaration of Equivalence (DoE) exists between NIST and that NMI.
* * * * *

Subpart B—Monitoring Network

■ 21. Amend § 58.10 by:
■ a. Revising paragraphs (a)(1) and (b)(10) and (13);
■ b. Adding paragraph (b)(14); and
■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a)(1) Beginning July 1, 2007, the State, or where applicable local, agency shall submit to the Regional Administrator an annual monitoring network plan which shall provide for the documentation of the establishment and maintenance of an air quality surveillance system that consists of a network of SLAMS monitoring stations that can include FRM and FEM monitors that are part of SLAMS, NCore, CSN, PAMS, and SPM stations. The plan shall include a statement of whether the operation of each monitor meets the requirements of appendices A, B, C, D, and E to this part, where applicable. The Regional Administrator may require additional information in support of this statement. The annual monitoring network plan must be made available for public inspection and comment for at least 30 days prior to submission to the EPA and the submitted plan shall include and address, as appropriate, any received comments.
* * * * *

(b) * * *

(10) Any monitors for which a waiver has been requested or granted by the EPA Regional Administrator as allowed for under appendix D or appendix E to this part. For those monitors where a waiver has been approved, the annual monitoring network plan shall include the date the waiver was approved.
* * * * *

(13) The identification of any $PM_{2.5}$ FEMs used in the monitoring agency's network where the data are not of sufficient quality such that data are not to be compared to the national ambient air quality standards (NAAQS). For required SLAMS where the agency identifies that the $PM_{2.5}$ Class III FEM does not produce data of sufficient quality for comparison to the NAAQS, the monitoring agency must ensure that an operating FRM or filter-based FEM meeting the sample frequency requirements described in § 58.12 or other Class III $PM_{2.5}$ FEM with data of sufficient quality is operating and reporting data to meet the network design criteria described in appendix D to this part.

(14) The identification of any site(s) intended to address being sited in an at-risk community where there are anticipated effects from sources in the area as required in section 4.7.1(b)(3) of appendix D to this part. An initial approach to the question of whether any new or moved sites are needed and to identify the communities in which they intend to add monitoring for meeting the requirement in this paragraph (b)(14), if applicable, shall be submitted in accordance with the requirements of section 4.7.1(b)(3) of appendix D to this part, which includes submission to the EPA Regional Administrator no later than July 1, 2024. Specifics on the resulting proposed new or moved sites for $PM_{2.5}$ network design to address at-risk communities, if applicable, would need to be detailed in annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2025. The plan shall provide for any required sites to be operational no later than 24 months from date of approval of a plan or January 1, 2027, whichever comes first.
* * * * *

(d) The State, or where applicable local, agency shall perform and submit to the EPA Regional Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. The network assessment must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of

susceptible individuals (*e.g.,* children with asthma) and other at-risk populations, and, for any sites that are being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby States and Tribes or health effects studies. The State, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The assessments are due every 5 years beginning July 1, 2010.

* * * * *

■ 22. Amend § 58.11 by revising paragraphs (a)(2) and (e) to read as follows:

§ 58.11 Network technical requirements.

(a) * * *

(2) Beginning January 1, 2009, State and local governments shall follow the quality assurance criteria contained in appendix A to this part that apply to SPM sites when operating any SPM site which uses an FRM or an FEM and meets the requirements of appendix E to this part, unless the Regional Administrator approves an alternative to the requirements of appendix A with respect to such SPM sites because meeting those requirements would be physically and/or financially impractical due to physical conditions at the monitoring site and the requirements are not essential to achieving the intended data objectives of the SPM site. Alternatives to the requirements of appendix A may be approved for an SPM site as part of the approval of the annual monitoring plan, or separately.

* * * * *

(e) State and local governments must assess data from Class III $PM_{2.5}$ FEM monitors operated within their network using the performance criteria described in table C–4 to subpart C of part 53 of this chapter, for cases where the data are identified as not of sufficient comparability to a collocated FRM, and the monitoring agency requests that the FEM data should not be used in comparison to the NAAQS. These assessments are required in the monitoring agency's annual monitoring network plan described in § 58.10(b) for cases where the FEM is identified as not of sufficient comparability to a collocated FRM. For these collocated $PM_{2.5}$ monitors, the performance criteria apply with the following additional provisions:

(1) The acceptable concentration range (Rj), $\mu g/m^3$ may include values down to 0 $\mu g/m^3$.

(2) The minimum number of test sites shall be at least one; however, the number of test sites will generally include all locations within an agency's network with collocated FRMs and FEMs.

(3) The minimum number of methods shall include at least one FRM and at least one FEM.

(4) Since multiple FRMs and FEMs may not be present at each site, the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than 36 consecutive months of data in total aggregated together.

(6) The key statistical metric to include in an assessment is the bias (both additive and multiplicative) of the $PM_{2.5}$ continuous FEM(s) compared to a collocated FRM(s). Correlation is required to be reported in the assessment, but failure to meet the correlation criteria, by itself, is not cause to exclude data from a continuous FEM monitor.

■ 23. Amend § 58.12 by revising paragraph (d)(1):

§ 58.12 Operating schedules.

* * * * *

(d) * * *

(1)(i) Manual $PM_{2.5}$ samplers at required SLAMS stations without a collocated continuously operating $PM_{2.5}$ monitor must operate on at least a 1-in-3 day schedule unless a waiver for an alternative schedule has been approved per paragraph (d)(1)(ii) of this section.

(ii) For SLAMS $PM_{2.5}$ sites with both manual and continuous $PM_{2.5}$ monitors operating, the monitoring agency may request approval for a reduction to 1-in-6 day $PM_{2.5}$ sampling or for seasonal sampling from the EPA Regional Administrator. Other requests for a reduction to 1-in-6 day $PM_{2.5}$ sampling or for seasonal sampling may be approved on a case-by-case basis. The EPA Regional Administrator may grant sampling frequency reductions after consideration of factors (including but not limited to the historical $PM_{2.5}$ data quality assessments, the location of current $PM_{2.5}$ design value sites, and their regulatory data needs) if the Regional Administrator determines that the reduction in sampling frequency will not compromise data needed for implementation of the NAAQS. Required SLAMS stations whose measurements determine the design value for their area and that are within plus or minus 10 percent of the annual NAAQS, and all required sites where one or more 24-hour values have exceeded the 24-hour NAAQS each year for a consecutive period of at least 3 years are required to maintain at least a 1-in-3 day sampling frequency until the design value no longer meets the criteria in this paragraph (d)(1)(ii) for 3 consecutive years. A continuously operating FEM $PM_{2.5}$ monitor satisfies the requirement in this paragraph (d)(1)(ii) unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS and the EPA Regional Administrator has approved that the data from that monitor may be excluded from comparison to the NAAQS.

(iii) Required SLAMS stations whose measurements determine the 24-hour design value for their area and whose data are within plus or minus 5 percent of the level of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if that area's design value for the annual NAAQS is less than the level of the annual $PM_{2.5}$ standard. A continuously operating FEM or $PM_{2.5}$ monitor satisfies the requirement in this paragraph (d)(1)(iii) unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS and the EPA Regional Administrator has approved that the data from that monitor may be excluded from comparison to the NAAQS. The daily schedule must be maintained until the referenced design values no longer meets the criteria in this paragraph (d)(1)(iii) for 3 consecutive years.

(iv) Changes in sampling frequency attributable to changes in design values shall be implemented no later than January 1 of the calendar year following the certification of such data as described in § 58.15.

* * * * *

■ 24. Revise § 58.15 to read as follows:

§ 58.15 Annual air monitoring data certification.

(a) The State, or where appropriate local, agency shall submit to the EPA Regional Administrator an annual air monitoring data certification letter to certify data collected by FRM and FEM monitors at SLAMS and SPM sites that meet criteria in appendix A to this part from January 1 to December 31 of the previous year. The head official in each monitoring agency, or his or her designee, shall certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of her or his knowledge, taking into consideration the quality assurance findings. The annual data certification letter is due by May 1 of each year.

(b) Along with each certification letter, the State shall submit to the Regional Administrator an annual

summary report of all the ambient air quality data collected by FRM and FEM monitors at SLAMS and SPM sites. The annual report(s) shall be submitted for data collected from January 1 to December 31 of the previous year. The annual summary serves as the record of the specific data that is the object of the certification letter.

(c) Along with each certification letter, the State shall submit to the Regional Administrator a summary of the precision and accuracy data for all ambient air quality data collected by FRM and FEM monitors at SLAMS and SPM sites. The summary of precision and accuracy shall be submitted for data collected from January 1 to December 31 of the previous year.

Subpart C—Special Purpose Monitors

■ 25. Amend § 58.20 by revising paragraphs (b) through (e) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(b) Any SPM data collected by an air monitoring agency using a Federal reference method (FRM) or Federal equivalent method (FEM) must meet the requirements of §§ 58.11 and 58.12 and appendix A to this part or an approved alternative to appendix A. Compliance with appendix E to this part is optional but encouraged except when the monitoring agency's data objectives are inconsistent with the requirements in appendix E. Data collected at an SPM using a FRM or FEM meeting the requirements of appendix A must be submitted to AQS according to the requirements of § 58.16. Data collected by other SPMs may be submitted. The monitoring agency must also submit to AQS an indication of whether each SPM reporting data to AQS monitor meets the requirements of appendices A and E.

(c) All data from an SPM using an FRM or FEM which has operated for more than 24 months are eligible for comparison to the relevant NAAQS, subject to the conditions of §§ 58.11(e) and 58.30, unless the air monitoring agency demonstrates that the data came from a particular period during which the requirements of appendix A, appendix C, or appendix E to this part were not met, subject to review and EPA Regional Office approval as part of the annual monitoring network plan described in § 58.10.

(d) If an SPM using an FRM or FEM is discontinued within 24 months of start-up, the Administrator will not base a NAAQS violation determination for the $PM_{2.5}$ or ozone NAAQS solely on data from the SPM.

(e) If an SPM using an FRM or FEM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, SO_2, NO_2, or 24-hour PM_{10} NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

* * * * *

■ 26. Amend appendix A to part 58 by:

■ a. Revising section 2.6.1 and adding sections 2.6.1.1 and 2.6.1.2;

■ b. Removing section 3.1.2.2 and redesignating sections 3.1.2.3, 3.1.2.4, 3.1.2.5, and 3.1.2.6 as sections 3.1.2.2, 3.1.2.3, 3.1.2.4, and 3.1.2.5, respectively;

■ c. Revising sections 3.1.3.3, 3.2.4, 4.2.1, and 4.2.5; and

■ d. In section 6 revising References (1), (4), (6), (7), (9), (10), and (11) and table A–1.

The revisions and additions read as follows:

Appendix A to Part 58—Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards

* * * * *

2.6.1 Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for CO, SO_2, NO, and NO_2 must be EPA Protocol Gases certified in accordance with one of the procedures given in Reference 4 of this appendix.

2.6.1.1 The concentrations of EPA Protocol Gas standards used for ambient air monitoring must be certified with a 95-percent confidence interval to have an analytical uncertainty of no more than ±2.0 percent (inclusive) of the certified concentration (tag value) of the gas mixture. The uncertainty must be calculated in accordance with the statistical procedures defined in Reference 4 of this appendix.

2.6.1.2 Specialty gas producers advertising certification with the procedures provided in Reference 4 of this appendix and distributing gases as ''EPA Protocol Gas'' for ambient air monitoring purposes must adhere to the regulatory requirements specified in 40 CFR 75.21(g) or not use ''EPA'' in any form of advertising. Monitoring organizations must provide information to the EPA on the specialty gas producers they use on an annual basis. PQAOs, when requested by the EPA, must participate in the EPA Ambient Air Protocol Gas Verification Program at least once every 5 years by sending a new unused standard to a designated verification laboratory.

* * * * *

3.1.3.3 Using audit gases that are verified against the NIST standard reference methods or special review procedures and validated per the certification periods specified in Reference 4 of this appendix (EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards) for CO, SO_2, and NO_2 and using O_3 analyzers that are verified quarterly against a standard reference photometer.

* * * * *

3.2.4 *$PM_{2.5}$ Performance Evaluation Program (PEP) Procedures.* The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the national performance evaluation program (NPEP) as described in section 2.4 of this appendix or a comparable program. A prescribed number of Performance evaluation sampling events will be performed annually within each PQAO. For PQAOs with less than or equal to five monitoring sites, five valid performance evaluation audits must be collected and reported each year. For PQAOs with greater than five monitoring sites, eight valid performance evaluation audits must be collected and reported each year. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and equal to or greater than 2 µg/m3. Siting of the PEP monitor must be consistent with section 3.2.3.4(c) of this appendix. However, any horizontal distance greater than 4 meters and any vertical distance greater than one meter must be reported to the EPA regional PEP coordinator. Additionally for every monitor designated as a primary monitor, a primary quality assurance organization must:

* * * * *

4.2.1 *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$, and Pb.* Precision is estimated via duplicate measurements from collocated samplers. It is recommended that the precision be aggregated at the PQAO level quarterly, annually, and at the 3-year level. The data pair would only be considered valid if both concentrations are greater than or equal to the minimum values specified in section 4(c) of this appendix. For each collocated data pair, calculate t_i, using equation 6 to this appendix:

Equation 6 to Section 4.2.1 of Appendix A

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i - Y_i)/2}}$$

Where X_i is the concentration from the primary sampler and Y_i is the concentration value from the audit sampler. The coefficient of variation upper bound is calculated using equation 7 to this appendix:

Equation 7 to Section 4.2.1 of Appendix A

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - \left(\sum_{i=1}^{k} t_i\right)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

Where k is the number of valid data pairs being aggregated, and $X^2_{0.1,k-1}$ is the 10th percentile of a chi-squared distribution with k-1 degrees of freedom. The factor of 2 in the denominator adjusts for the fact that each t_i is calculated from two values with error.

* * * * *

4.2.5 *Performance Evaluation Programs Bias Estimate for $PM_{2.5}$.* The bias estimate is calculated using the PEP audits described in section 3.2.4. of this appendix. The bias estimator is based on, s_i, the absolute difference in concentrations divided by the square root of the PEP concentration.

Equation 8 to Section 4.2.5 of Appendix A

$$100 \times \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}}$$

* * * * *

6. References

(1) American National Standard Institute—Quality Management Systems For Environmental Information And Technology Programs—Requirements With Guidance For Use. ASQ/ANSI E4–2014. February 2014. Available from ANSI Webstore *https://webstore.ansi.org/.*

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(4) EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards. EPA–600/R–12/531. May, 2012. Available from U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Research Triangle Park NC 27711. *https://www.epa.gov/nscep.*

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(6) List of Designated Reference and Equivalent Methods. Available from U.S. Environmental Protection Agency, Center for Environmental Measurements and Modeling, Air Methods and Characterization Division, MD–D205–03, Research Triangle Park, NC 27711. *https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants.*

(7) Transfer Standards for the Calibration of Ambient Air Monitoring Analyzers for Ozone. EPA–454/B–13–004 U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, October, 2013. *https://www.epa.gov/sites/default/files/2020-09/documents/ozonetransferstandardguidance.pdf.*

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(9) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1—A Field Guide to Environmental Quality Assurance. EPA–600/R–94/038a. April 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.*

(10) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Ambient Air Quality Monitoring Program Quality System Development. EPA–454/B–13–003. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.*

(11) National Performance Evaluation Program Standard Operating Procedures. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#npep.*

TABLE A–1 TO SECTION 6 OF APPENDIX A—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR NAAQS RELATED CRITERIA POLLUTANT MONITORS

Method	Assessment method	Coverage	Minimum frequency	Parameters reported	AQS assessment type
Gaseous Methods (CO, NO_2, SO_2, O_3):					

TABLE A–1 TO SECTION 6 OF APPENDIX A—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR NAAQS RELATED CRITERIA POLLUTANT MONITORS—Continued

Method	Assessment method	Coverage	Minimum frequency	Parameters reported	AQS assessment type
One-Point QC for SO_2, NO_2, O_3, CO.	Response check at concentration 0.005–0.08 ppm SO_2, NO_2, O_3, and. 0.5 and 5 ppm CO	Each analyzer	Once per 2 weeks [5] ..	Audit concentration [1] and measured concentration.[2].	One-Point QC.
Annual performance evaluation for SO_2, NO_2, O_3, CO.	See section 3.1.2 of this appendix.	Each analyzer	Once per year	Audit concentration [1] and measured concentration [2] for each level.	Annual PE.
NPAP for SO_2, NO_2, O_3, CO.	Independent Audit	20% of sites each year.	Once per year	Audit concentration[1] and measured concentration [2] for each level.	NPAP.
Particulate Methods:					
Continuous [4] method—collocated quality control sampling $PM_{2.5}$.	Collocated samplers	15%	1-in-12 days	Primary sampler concentration and duplicate sampler concentration.[3].	No Transaction reported as raw data.
Manual method—collocated quality control sampling PM_{10}, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Collocated samplers	15%	1-in-12 days	Primary sampler concentration and duplicate sampler concentration.[3].	No Transaction reported as raw data.
Flow rate verification PM_{10} (low Vol) $PM_{2.5}$, Pb-PM_{10}.	Check of sampler flow rate.	Each sampler	Once every month [5] ..	Audit flow rate and measured flow rate indicated by the sampler.	Flow Rate Verification.
Flow rate verification PM_{10} (High-Vol), Pb-TSP.	Check of sampler flow rate.	Each sampler	Once every quarter [5]	Audit flow rate and measured flow rate indicated by the sampler.	Flow Rate Verification.
Semi-annual flow rate audit PM_{10}, TSP, PM_{10}–2.5, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months [5].	Audit flow rate and measured flow rate indicated by the sampler.	Semi Annual Flow Rate Audit.
Pb analysis audits Pb-TSP, Pb-PM_{10}.	Check of analytical system with Pb audit strips/filters.	Analytical	Once each quarter [5] ..	Measured value and audit value (ug Pb/filter) using AQS unit code 077.	Pb Analysis Audits.
Performance Evaluation Program $PM_{2.5}$.	Collocated samplers	(1) 5 valid audits for primary QA orgs, with ≤5 sites. (2) 8 valid audits for primary QA orgs, with >5 sites. (3) All samplers in 6 years.	Distributed over all 4 quarters [5].	Primary sampler concentration and performance evaluation sampler concentration.	PEP.
Performance Evaluation Program Pb-TSP, Pb-PM_{10}.	Collocated samplers	(1) 1 valid audit and 4 collocated samples for primary QA orgs, with ≤5 sites. (2) 2 valid audits and 6 collocated samples for primary QA orgs with >5 sites.	Distributed over all 4 quarters [5].	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.	PEP.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable for open path analyzers.
[3] Both primary and collocated sampler values are reported as raw data.
[4] $PM_{2.5}$ is the only particulate criteria pollutant requiring collocation of continuous and manual primary monitors.
[5] EPA's recommended maximum number of days that should exist between checks to ensure that the checks are routinely conducted over time and to limit data impacts resulting from a failed check.

* * * * *

■ 27. Amend appendix B to part 58 by:

■ a. Revising section 2.6.1 and adding sections 2.6.1.1 and 2.6.1.2;

■ b. Removing and reserving section 3.1.2.2;

■ c. Revising sections 3.1.3.3 and 3.2.4;
■ d. Adding sections 3.2.4.1 through 3.2.4.3;
■ e. Revising sections 4.2.1, and 4.2.5; and
■ f. In section 6 revising References (1), (4), (6), (7), (9), (10), and (11) and table B–1.

The revisions and additions read as follows:

Appendix B to Part 58—Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring

* * * * *

2.6.1 Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for CO, SO_2, NO, and NO_2 must be EPA Protocol Gases certified in accordance with one of the procedures given in Reference 4 of this appendix.

2.6.1.1 The concentrations of EPA Protocol Gas standards used for ambient air monitoring must be certified with a 95-percent confidence interval to have an analytical uncertainty of no more than ±2.0 percent (inclusive) of the certified concentration (tag value) of the gas mixture. The uncertainty must be calculated in accordance with the statistical procedures defined in Reference 4 of this appendix.

2.6.1.2 Specialty gas producers advertising certification with the procedures provided in Reference 4 of this appendix and distributing gases as ''EPA Protocol Gas'' for ambient air monitoring purposes must adhere to the regulatory requirements specified in 40 CFR 75.21(g) or not use ''EPA'' in any form of advertising. The PSD PQAOs must provide information to the PSD reviewing authority on the specialty gas producers they use (or will use) for the duration of the PSD monitoring project. This information can be provided in the QAPP or monitoring plan but must be updated if there is a change in the specialty gas producers used.

* * * * *

3.1.3.3 Using audit gases that are verified against the NIST standard reference methods or special review procedures and validated per the certification periods specified in Reference 4 of this appendix (EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards) for CO, SO_2, and NO_2 and using O_3 analyzers that are verified quarterly against a standard reference photometer.

* * * * *

3.2.4 *$PM_{2.5}$ Performance Evaluation Program (PEP) Procedures.* The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the NPEP as described in section 2.4 of this appendix or a comparable program. Performance evaluations will be performed annually within each PQAO. For PQAOs with less than or equal to five monitoring sites, five valid performance evaluation audits must be collected and reported each year. For PQAOs with greater than five monitoring sites, eight valid performance evaluation audits must be collected and reported each year. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and equal to or greater than 2 µg/m3. Siting of the PEP monitor must be consistent with section 3.2.3.4(c) of this appendix. However, any horizontal distance greater than 4 meters and any vertical distance greater than one meter must be reported to the EPA regional PEP coordinator. Additionally for every monitor designated as a primary monitor, a primary quality assurance organization must:

3.2.4.1 Have each method designation evaluated each year; and,

3.2.4.2 Have all FRM and FEM samplers subject to a PEP audit at least once every 6 years, which equates to approximately 15 percent of the monitoring sites audited each year.

3.2.4.3 Additional information concerning the PEP is contained in Reference 10 of this appendix. The calculations for evaluating bias between the primary monitor and the performance evaluation monitor for $PM_{2.5}$ are described in section 4.2.5 of this appendix.

* * * * *

4.2.1 *Collocated Quality Control Sampler Precision Estimate for PM_{10}, $PM_{2.5}$, and Pb.* Precision is estimated via duplicate measurements from collocated samplers. It is recommended that the precision be aggregated at the PQAO level quarterly, annually, and at the 3-year level. The data pair would only be considered valid if both concentrations are greater than or equal to the minimum values specified in section 4(c) of this appendix. For each collocated data pair, calculate t_i, using equation 6 to this appendix:

Equation 6 to Section 4.2.1 of Appendix B

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i - Y_i)/2}}$$

Where X_i is the concentration from the primary sampler and Y_i is the concentration value from the audit sampler. The coefficient of variation upper bound is calculated using equation 7 to this appendix:

Equation 7 to Section 4.2.1 of Appendix B

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - \left(\sum_{i=1}^{k} t_i\right)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

Where k is the number of valid data pairs being aggregated, and $X^2_{0.1,k-1}$ is the 10th percentile of a chi-squared distribution with k-1 degrees of freedom. The factor of 2 in the denominator adjusts for the fact that

each t_i is calculated from two values with error.

* * * * *

4.2.5 *Performance Evaluation Programs Bias Estimate for $PM_{2.5}$.* The bias estimate is calculated using the PEP audits described in section 3.2.4. of this appendix. The bias estimator is based on, s_i, the absolute difference in concentrations divided by the square root of the PEP concentration.

Equation 8 to Section 4.2.5 of Appendix B

$$100 \times \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}}$$

* * * * *

6. References

(1) American National Standard Institute—Quality Management Systems For Environmental Information And Technology Programs—Requirements With Guidance For Use. ASQ/ANSI E4–2014. February 2014. Available from ANSI Webstore *https://webstore.ansi.org/.*

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(4) EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards. EPA–600/R–12/531. May, 2012. Available from U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Research Triangle Park NC 27711. *https://www.epa.gov/nscep.*

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(6) List of Designated Reference and Equivalent Methods. Available from U.S. Environmental Protection Agency, Center for Environmental Measurements and Modeling, Air Methods and Characterization Division, MD–D205–03, Research Triangle Park, NC 27711. *https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants.*

(7) Transfer Standards for the Calibration of Ambient Air Monitoring Analyzers for Ozone. EPA–454/B–13–004 U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, October, 2013. *https://www.epa.gov/sites/default/files/2020-09/documents/ozonetransferstandardguidance.pdf.*

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(9) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1—A Field Guide to Environmental Quality Assurance. EPA–600/R–94/038a. April 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.*

(10) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Ambient Air Quality Monitoring Program Quality System Development. EPA–454/B–13–003. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.*

(11) National Performance Evaluation Program Standard Operating Procedures. *https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#npep.*

TABLE B–1 TO SECTION 6 OF APPENDIX B- MINIMUM DATA ASSESSMENT REQUIREMENTS FOR NAAQS RELATED CRITERIA POLLUTANT PSD MONITORS

Method	Assessment method	Coverage	Minimum frequency	Parameters reported	AQS Assessment type
Gaseous Methods (CO, NO_2, SO_2, O_3):					
One-Point QC for SO_2, NO_2, O_3, CO.	Response check at concentration 0.005–0.08 ppm SO_2, NO_2, O_3, & 0.5 and 5 ppm CO.	Each analyzer	Once per 2 weeks[5] ...	Audit concentration[1] and measured concentration[2].	One-Point QC.
Quarterly performance evaluation for SO_2, NO_2, O_3, CO.	See section 3.1.2 of this appendix.	Each analyzer	Once per quarter[5]	Audit concentration[1] and measured concentration[2] for each level.	Annual PE.
NPAP for SO_2, NO_2, O_3, CO[3].	Independent Audit	Each primary monitor	Once per year	Audit concentration[1] and measured concentration[2] for each level.	NPAP.
Particulate Methods:					
Collocated sampling PM_{10}, $PM_{2.5}$, Pb.	Collocated samplers	1 per PSD Network per pollutant.	Every 6 days or every 3 days if daily monitoring required.	Primary sampler concentration and duplicate sampler concentration[4].	No Transaction reported as raw data.
Flow rate verification PM_{10}, $PM_{2.5}$, Pb.	Check of sampler flow rate.	Each sampler	Once every month[5] ...	Audit flow rate and measured flow rate indicated by the sampler.	Flow Rate Verification.
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, Pb.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months or beginning, middle and end of monitoring[5].	Audit flow rate and measured flow rate indicated by the sampler.	Semi Annual Flow Rate Audit.

TABLE B–1 TO SECTION 6 OF APPENDIX B- MINIMUM DATA ASSESSMENT REQUIREMENTS FOR NAAQS RELATED CRITERIA POLLUTANT PSD MONITORS—Continued

Method	Assessment method	Coverage	Minimum frequency	Parameters reported	AQS Assessment type
Pb analysis audits Pb-TSP, Pb-PM_{10}.	Check of analytical system with Pb audit strips/filters.	Analytical	Each quarter[5]	Measured value and audit value (ug Pb/filter) using AQS unit code 077 for parameters:. 14129—Pb (TSP) LC FRM/FEM. 85129—Pb (TSP) LC Non-FRM/FEM..	Pb Analysis Audits.
Performance Evaluation Program $PM_{2.5}$[3].	Collocated samplers	(1) 5 valid audits for PQAOs with <= 5 sites.. (2) 8 valid audits for PQAOs with > 5 sites.. (3) All samplers in 6 years.	Over all 4 quarters[5] ..	Primary sampler concentration and performance evaluation sampler concentration.	PEP.
Performance Evaluation Program Pb[3].	Collocated samplers	(1) 1 valid audit and 4 collocated samples for PQAOs, with <=5 sites.. (2) 2 valid audits and 6 collocated samples for PQAOs with >5 sites..	Over all 4 quarters[5] ..	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.	PEP.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable for open path analyzers.
[3] NPAP, $PM_{2.5}$, PEP, and Pb-PEP must be implemented if data is used for NAAQS decisions otherwise implementation is at PSD reviewing authority discretion.
[4] Both primary and collocated sampler values are reported as raw data
[5] A maximum number of days should be between these checks to ensure the checks are routinely conducted over time and to limit data impacts resulting from a failed check.

■ 28. Amend appendix C to part 58 by:
■ a. Adding sections 2.2 and 2.2.1 through 2.2.19;
■ b. Removing and reserving sections 2.4, 2.4.1;
■ c. Removing sections 2.4.1.1 through 2.4.1.7; and
■ d. Revising section 2.7.1.

The additions and revision reads as follows:

Appendix C to Part 58—Ambient Air Quality Monitoring Methodology

* * * * *

2.2 PM_{10}, $PM_{2.5}$, or $PM_{10-2.5}$ continuous FEMs with existing valid designations may be calibrated using network data from collocated FRM and continuous FEM data under the following provisions:

2.2.1 Data to demonstrate a calibration may include valid data from State, local, or Tribal air agencies or data collected by instrument manufacturers in accordance with 40 CFR 53.35 or other data approved by the Administrator.

2.2.2 A request to update a designated methods calibration may be initiated by the instrument manufacturer of record or the EPA Administrator. State, local, Tribal, and multijusistincional organizations of these entities may work with an instrument manufacture to update a designated method calibration.

2.2.3 Requests for approval of an updated PM_{10}, $PM_{2.5}$, or $PM_{10-2.5}$ continuous FEM calibration must meet the general submittal requirements of section 2.7 of this appendix.

2.2.4 Data included in the request should represent a subset of representative locations where the method is operational. For cases with a small number of collocated FRMs and continuous FEMs sites, an updated candidate calibration may be limited to the sites where both methods are in use.

2.2.5 Data included in a candidate method updated calibration may include a subset of sites where there is a large grouping of sites in one part of the country such that the updated calibration would be representative of the country as a whole.

2.2.6 Improvements should be national in scope and ideally implemented through a firmware change.

2.2.7 The goal of a change to a methods calibration is to increase the number of sites meeting measurements quality objectives of the method as identified in section 2.3.1.1 of appendix A to this part.

2.2.8 For meeting measurement quality objectives (MQOs), the primary objective is to meet the bias goal as this statistic will likely have the most influence on improving the resultant data collected.

2.2.9 Precision data are to be included, but so long as precision data are at least as good as existing network data or meet the MQO referenced in section 2.2.8 of this appendix, no further work is necessary with precision.

2.2.10 Data available to use may include routine primary and collocated data.

2.2.11 Audit data may be useful to confirm the performance of a candidate updated calibration but should not be used as the basis of the calibration to keep the independence of the audit data.

2.2.12 Data utilized as the basis of the updated calibration may be obtained by accessing EPA's AQS database or future analogous EPA database.

2.2.13 Years of data to use in a candidate method calibration should include two recent years where we are past the certification period for the previous year's data, which is May 1 of each year.

2.2.14 Data from additional years is to be used to test an updated calibration such that the calibration is independent of the test years of interest. Data from these additional years need to minimally demonstrate that a larger number of sites are expected to meet bias MQO especially at sites near the level of the NAAQS for the PM indicator of interest.

2.2.15 Outliers may be excluded using routine outlier tests.

2.2.16 The range of data used in a calibration may include all data available or alternatively use data in the range from the lowest measured data available up to 125% of the 24-hour NAAQS for the PM indicator of interest.

2.2.17 Other improvements to a PM continuous method may be included as part of a recommended update so long as appropriate testing is conducted with input from EPA's Office of Research and Development (ORD) Reference and Equivalent (R&E) Methods Designation program.

2.2.18 EPA encourages early communication by instrument manufacturers considering an update to a PM method. Instrument companies should initiate such dialogue by contacting EPA's ORD R&E Methods Designation program. The contact information for this can be found at 40 CFR 53.4.

2.2.19 Manufacturers interested in improving instrument's performance through an updated factory calibration must submit a written modification request to EPA with supporting rationale. Because the testing requirements and acceptance criteria of any field and/or lab tests can depend upon the nature and extent of the intended modification, applicants should contact EPA's R&E Methods Designation program for guidance prior to development of the modification request.

* * * * *

2.7.1 Requests for approval under sections 2.2, 2.4, 2.6.2, or 2.8 of this appendix must be submitted to: Director, Center for Environmental Measurement and Modeling, Reference and Equivalent Methods Designation Program (MD–D205–03), U.S. Environmental Protection Agency, P.O. Box 12055, Research Triangle Park, North Carolina 27711.

■ 29. Amend appendix D to part 58 by revising sections 1 and 1.1(b), the introductory text before the table in section 4.7.1(a), and sections 4.7.1(b)(3) and 4.7.2 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

1. Monitoring Objectives and Spatial Scales

The purpose of this appendix is to describe monitoring objectives and general criteria to be applied in establishing the required SLAMS ambient air quality monitoring stations and for choosing general locations for additional monitoring sites. This appendix also describes specific requirements for the number and location of FRM and FEM sites for specific pollutants, NCore multipollutant sites, PM_{10} mass sites, $PM_{2.5}$ mass sites, chemically-speciated $PM_{2.5}$ sites, and O_3 precursor measurements sites (PAMS). These criteria will be used by EPA in evaluating the adequacy of the air pollutant monitoring networks.

1.1 * * *

(b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM and FEM monitors for NAAQS pollutants will be used for comparing an area's air pollution levels against the NAAQS. Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially NCore station data, will be used to evaluate the regional air quality models used in developing emission strategies, and to track trends in air pollution abatement control measures' impact on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions.

* * * * *

4.7.1 * * *

(a) State and where applicable, local, agencies must operate the minimum number of required $PM_{2.5}$ SLAMS sites listed in table D–5 to this appendix. The NCore sites are expected to complement the $PM_{2.5}$ data collection that takes place at non-NCore SLAMS sites, and both types of sites can be used to meet the minimum $PM_{2.5}$ network requirements. For many State and local networks, the total number of $PM_{2.5}$ sites needed to support the basic monitoring objectives of providing air pollution data to the general public in a timely manner, support compliance with ambient air quality standards and emission strategy development, and support for air pollution research studies will include more sites than the minimum numbers required in table D–5 to this appendix. Deviations from these $PM_{2.5}$ monitoring requirements must be approved by the EPA Regional Administrator.

* * * * *

(b) * * *

(3) For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community with poor air quality, particularly where there are anticipated effects from sources in the area (*e.g.,* a major industrial area, point source(s), port, rail yard, airport, or other transportation facility or corridor).

* * * * *

4.7.2 Requirement for Continuous $PM_{2.5}$ Monitoring. The State, or where appropriate, local agencies must operate continuous $PM_{2.5}$ analyzers equal to at least one-half (round up) the minimum required sites listed in table D–5 to this appendix. At least one required continuous analyzer in each MSA must be collocated with one of the required FRM/FEM monitors, unless at least one of the required FRM/FEM monitors is itself a continuous FEM monitor in which case no collocation requirement applies. State and local air monitoring agencies must use methodologies and quality assurance/quality control (QA/QC) procedures approved by the EPA Regional Administrator for these required continuous analyzers.

* * * * *

■ 30. Revise appendix E to part 58 to read as follows:

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

1. Introduction

1.1 Applicability

(a) This appendix contains specific location criteria applicable to ambient air quality monitoring probes, inlets, and optical paths of SLAMS, NCore, PAMS, and other monitor types whose data are intended to be used to determine compliance with the NAAQS. These specific location criteria are relevant after the general location has been selected based on the monitoring objectives and spatial scale of representation discussed in appendix D to this part. Monitor probe material and sample residence time requirements are also included in this appendix. Adherence to these siting criteria is necessary to ensure the uniform collection of compatible and comparable air quality data.

(b) The probe and monitoring path siting criteria discussed in this appendix must be followed to the maximum extent possible. It is recognized that there may be situations where some deviation from the siting criteria may be necessary. In any such case, the reasons must be thoroughly documented in a written request for a waiver that describes whether the resulting monitoring data will be representative of the monitoring area and how and why the proposed or existing siting must deviate from the criteria. This documentation should help to avoid later questions about the validity of the resulting monitoring data. Conditions under which the EPA would consider an application for waiver from these siting criteria are discussed in section 4 of this appendix.

(c) The pollutant-specific probe and monitoring path siting criteria generally apply to all spatial scales except where noted otherwise. Specific siting criteria that are phrased with ''shall'' or ''must'' are defined as requirements and exceptions must be granted through the waiver provisions. However, siting criteria that are phrased with ''should'' are defined as goals to meet for consistency but are not requirements.

2. Monitors and Samplers with Probe Inlets

2.1 Horizontal and Vertical Placement

(a) For O_3 and SO_2 monitoring, and for neighborhood or larger spatial scale Pb, PM_{10}, $PM_{10–2.5}$, $PM_{2.5}$, NO_2, and CO sites, the probe must be located greater than or equal to 2.0 meters and less than or equal to 15 meters above ground level.

(b) Middle scale CO and NO_2 monitors must have sampler inlets greater than or equal to 2.0 meters and less than or equal to 15 meters above ground level.

(c) Middle scale $PM_{10–2.5}$ sites are required to have sampler inlets greater than or equal to 2.0 meters and less than or equal to 7.0 meters above ground level.

(d) Microscale Pb, PM_{10}, $PM_{10–2.5}$, and $PM_{2.5}$ sites are required to have sampler inlets greater than or equal to 2.0 meters and less than or equal to 7.0 meters above ground level.

(e) Microscale near-road NO_2 monitoring sites are required to have sampler inlets greater than or equal to 2.0 meters and less than or equal to 7.0 meters above ground level.

(f) The probe inlets for microscale carbon monoxide monitors that are being used to

measure concentrations near roadways must be greater than or equal to 2.0 meters and less than or equal to 7.0 meters above ground level. Those probe inlets for microscale carbon monoxide monitors measuring concentrations near roadways in downtown areas or urban street canyons must be greater than or equal to 2.5 meters and less than or equal to 3.5 meters above ground level. The probe must be at least 1.0 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe is located near the side of a building or wall, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

2.2 Spacing From Minor Sources

(a) It is important to understand the monitoring objective for a particular site in order to interpret this requirement. Local minor sources of a primary pollutant, such as SO_2, lead, or particles, can cause high concentrations of that particular pollutant at a monitoring site. If the objective for that monitoring site is to investigate these local primary pollutant emissions, then the site will likely be properly located nearby. This type of monitoring site would, in all likelihood, be a microscale-type of monitoring site. If a monitoring site is to be used to determine air quality over a much larger area, such as a neighborhood or city, a monitoring agency should avoid placing a monitor probe inlet near local, minor sources, because a plume from a local minor source should not be allowed to inappropriately impact the air quality data collected at a site. Particulate matter sites should not be located in an unpaved area unless there is vegetative ground cover year-round, so that the impact of windblown dusts will be kept to a minimum.

(b) Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of O_3 in the vicinity of probes for O_3. To minimize these potential interferences from nearby minor sources, the probe inlet should be placed at a distance from furnace or incineration flues or other minor sources of SO_2 or NO. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel.

2.3 Spacing From Obstructions

(a) Obstacles may scavenge SO_2, O_3, or NO_2, and can act to restrict airflow for any pollutant. To avoid this interference, the probe inlet must have unrestricted airflow pursuant to paragraph (b) of this section and should be located at a distance from obstacles. The horizontal distance from the obstacle to the probe inlet must be at least twice the height that the obstacle protrudes above the probe inlet. An obstacle that does not meet the minimum distance requirement is considered an obstruction that restricts airflow to the probe inlet. The EPA does not generally consider objects or obstacles such as flag poles or site towers used for NOy convertors and meteorological sensors, etc. to be deemed obstructions.

(b) A probe inlet located near or along a vertical wall is undesirable because air moving along the wall may be subject to removal mechanisms. A probe inlet must have unrestricted airflow with no obstructions (as defined in paragraph (a) of this section) in a continuous arc of at least 270 degrees. An unobstructed continuous arc of 180 degrees is allowable when the applicable network design criteria specified in appendix D of this part require monitoring in street canyons and the probe is located on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential. For particle sampling, there must be a minimum of 2.0 meters of horizontal separation from walls, parapets, and structures for rooftop site placement.

(c) A sampling station with a probe inlet located closer to an obstacle than required by the criteria in this section should be classified as middle scale or microscale, rather than neighborhood or urban scale, since the measurements from such a station would more closely represent these smaller scales.

(d) For near-road monitoring stations, the monitor probe shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment.

2.4 Spacing From Trees

(a) Trees can provide surfaces for SO_2, O_3, or NO_2 adsorption or reactions and surfaces for particle deposition. Trees can also act as obstructions in locations where the trees are between the air pollutant sources or source areas and the monitoring site and where the trees are of a sufficient height and leaf canopy density to interfere with the normal airflow around the probe inlet. To reduce this possible interference/obstruction, the probe inlet should be 20 meters or more from the drip line of trees and must be at least 10 meters from the drip line of trees. If a tree or group of trees is an obstacle, the probe inlet must meet the distance requirements of section 2.3 of this appendix.

(b) The scavenging effect of trees is greater for O_3 than for other criteria pollutants. Monitoring agencies must take steps to consider the impact of trees on ozone monitoring sites and take steps to avoid this problem.

(c) Beginning January 1, 2024, microscale sites of any air pollutant shall have no trees or shrubs located at or above the line-of-sight fetch between the probe and the source under investigation, *e.g.,* a roadway or a stationary source.

2.5 Spacing From Roadways

TABLE E–1 TO SECTION 2.5 OF APPENDIX E—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE (O_3) AND OXIDES OF NITROGEN (NO, NO_2, NO_X, NO_y)

Roadway average daily traffic, vehicles per day	Minimum distance[1 3] (meters)	Minimum distance[1 2 3] (meters)
≤1,000	10	10
10,000	10	20
15,000	20	30
20,000	30	40
40,000	50	60
70,000	100	100
≥110,000	250	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count./ TNOTE≤

[2] Applicable for ozone monitors whose placement was not approved as of December 18, 2006.

[3] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

2.5.1 Spacing for Ozone Probes

In siting an O_3 monitor, it is important to minimize destructive interferences from sources of NO, since NO readily reacts with O_3. Table E–1 of this appendix provides the required minimum separation distances between a roadway and a probe inlet for various ranges of daily roadway traffic. A sampling site with a monitor probe located closer to a roadway than allowed by the Table E–1 requirements should be classified as middle scale or microscale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent these smaller scales.

2.5.2 Spacing for Carbon Monoxide Probes

(a) Near-road microscale CO monitoring sites, including those located in downtown areas, urban street canyons, and other near-road locations such as those adjacent to highly trafficked roads, are intended to provide a measurement of the influence of the immediate source on the pollution exposure on the adjacent area.

(b) Microscale CO monitor probe inlets in downtown areas or urban street canyon locations shall be located a minimum distance of 2.0 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane.

(c) Microscale CO monitor probe inlets in downtown areas or urban street canyon locations shall be located at least 10 meters from an intersection, preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between

them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections.

(d) Neighborhood scale CO monitor probe inlets in downtown areas or urban street canyon locations shall be located according to the requirements in Table E–2 of this appendix.

TABLE E–2 TO SECTION 2.5.2 OF APPENDIX E—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE

Roadway average daily traffic, vehicles per day	Minimum distance [1] [2] (meters)
≤10,000	10
15,000	25
20,000	45
30,000	80
40,000	115
50,000	135
≥60,000	150

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

2.5.3 Spacing for Particulate Matter ($PM_{2.5}$, $PM_{2.5–10}$, PM_{10}, Pb) Inlets

(a) Since emissions associated with the operation of motor vehicles contribute to urban area particulate matter ambient levels, spacing from roadway criteria are necessary for ensuring national consistency in PM sampler siting.

(b) The intent is to locate localized hot-spot sites in areas of highest concentrations, whether it be caused by mobile or multiple stationary sources. If the area is primarily affected by mobile sources and the maximum concentration area(s) is judged to be a traffic corridor or street canyon location, then the monitors should be located near roadways with the highest traffic volume and at separation distances most likely to produce the highest concentrations. For microscale traffic corridor sites, the location must be greater than or equal 5.0 meters and less than or equal to 15 meters from the major roadway. For the microscale street canyon site, the location must be greater than or equal 2.0 meters and less than or equal to 10 meters from the roadway. For the middle scale site, a range of acceptable distances from the roadway is shown in Figure E–1 of this appendix. This figure also includes separation distances between a roadway and neighborhood or larger scale sites by default. Any PM probe inlet at a site, 2.0 to 15 meters high, and further back than the middle scale requirements will generally be neighborhood, urban or regional scale. For example, according to Figure E–1 of this appendix, if a PM sampler is primarily influenced by roadway emissions and that sampler is set back 10 meters from a 30,000 ADT (average daily traffic) road, the site should be classified as microscale, if the sampler's inlet height is between 2.0 and 7.0 meters. If the sampler's inlet height is between 7.0 and 15 meters, the site should be classified as middle scale. If the sampler is 20 meters from the same road, it will be classified as middle scale; if 40 meters, neighborhood scale; and if 110 meters, an urban scale.

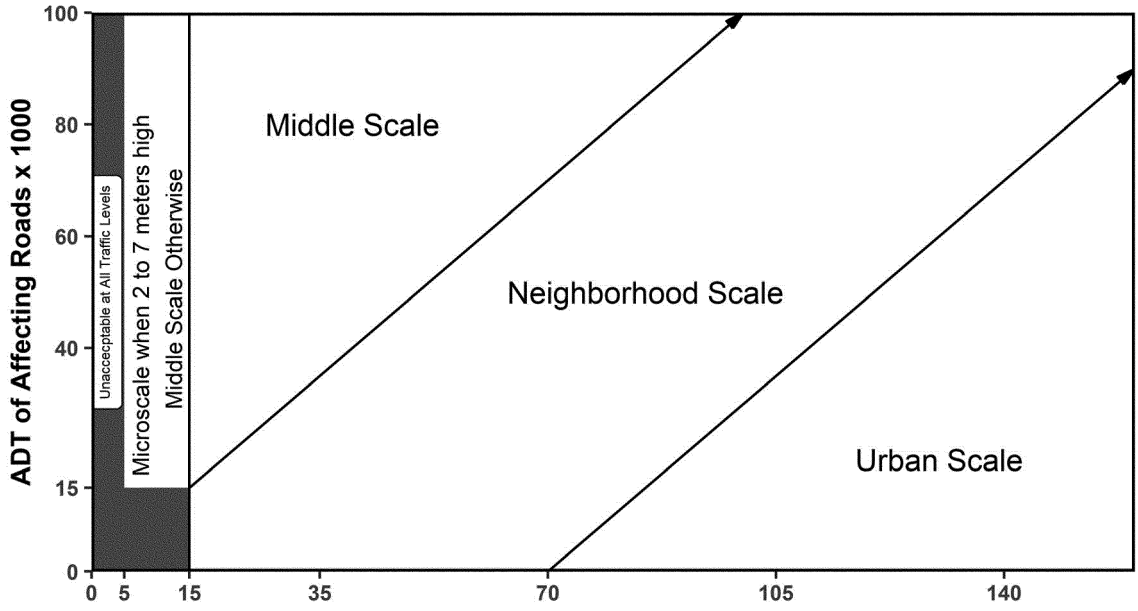

Figure E-1. Distance of PM Samplers to nearest traffic lane (meters)

Notes: Microscale street canyon sites must reside between 2 and 10 meters from the roadway.
Near-Road sites must be within 50 meters of the roadway.
The slopes of the lines between monitoring scales are one to one.

2.5.4 Spacing for Nitrogen Dioxide (NO_2) Probes

(a) In siting near-road NO_2 monitors as required in section 4.3.2 of appendix D of this part, the monitor probe shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment. Where possible, the near-road NO_2 monitor probe should be within 20 meters of the target road segment.

(b) In siting NO_2 monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E–1 of this appendix provides the required minimum separation distances between a roadway and a probe inlet for various ranges of daily roadway traffic. A site with a monitor probe located closer to a roadway than allowed by the Table E–1 requirements should be classified

as microscale or middle scale rather than neighborhood or urban scale.

2.6 Probe Material and Pollutant Sampler Residence Time

(a) For the reactive gases (SO_2, NO_2, and O_3), approved probe materials must be used for monitors. Studies[25 34] have been conducted to determine the suitability of materials such as polypropylene, polyethylene, polyvinyl chloride, Tygon®, aluminum, brass, stainless steel, copper, borosilicate glass, polyvinylidene fluoride (PVDF), polytetrafluoroethylene (PTFE), perfluoroalkoxy (PFA), and fluorinated ethylene propylene (FEP) for use as intake sampling lines. Of the above materials, only borosilicate glass, PVDF, PTFE, PFA, and FEP have been found to be acceptable for use as intake sampling lines for all the reactive gaseous pollutants. Furthermore, the EPA [25] has specified borosilicate glass, FEP Teflon®, or their equivalents as the only acceptable probe materials for delivering test atmospheres in the determination of reference or equivalent methods. Therefore, borosilicate glass, PVDF, PTFE, PFA, FEP, or their equivalents must be the only material in the sampling train (from probe inlet to the back of the monitor) that can be in contact with the ambient air sample for reactive gas monitors. Nafion™, which is composed primarily of PTFE, can be considered equivalent to PTFE; it has been shown in tests to exhibit virtually no loss of ozone at 20-second residence times.[35]

(b) For volatile organic compound (VOC) monitoring at PAMS, FEP Teflon® is unacceptable as the probe material because of VOC adsorption and desorption reactions on the FEP Teflon®. Borosilicate glass, stainless steel, or their equivalents are the acceptable probe materials for VOC and carbonyl sampling. Care must be taken to ensure that the sample residence time is kept to 20 seconds or less.

(c) No matter how nonreactive the sampling probe material is initially, after a period of use, reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses, even in the most inert probe material, when the residence time exceeds 20 seconds.[26] Other studies [27 28]indicate that a 10-second or less residence time is easily achievable. Therefore, sampling probes for all reactive gas monitors for SO_2, NO_2, and O_3 must have a sample residence time less than 20 seconds.

2.7 Summary

Table E–3 of this appendix presents a summary of the general requirements for probe siting criteria with respect to distances and heights. Table E–3 requires different elevation distances above the ground for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor or probe inlet. The differences in the specified range of heights are based on the vertical concentration gradients. For source oriented and near-road monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a single manifold for monitoring more than one pollutant.

TABLE E–3 TO SECTION 2.7 OF APPENDIX E—SUMMARY OF PROBE SITING CRITERIA

Pollutant	Scale [9]	Height from ground to probe [8] (meters)	Horizontal or vertical distance from supporting structures [1 8] to probe inlet (meters)	Distance from drip line of trees to probe [8] (meters)	Distance from roadways to probe [8] (meters)
SO_2 [2 3 4 5]	Middle, Neighborhood, Urban, and Regional.	2.0–15	≥1.0	≥10	N/A.
CO [3 4 6]	Micro [downtown or street canyon sites].	2.5–3.5			2.0–10 for downtown areas or street canyon microscale.
	Micro [Near-Road sites]	2.0–7.0	≥1.0	≥10	≤50 for near-road microscale.
	Middle and Neighborhood	2.0–15			*See* Table E–2 of this appendix for middle and neighborhood scales.
O_3 [2 3 4]	Middle, Neighborhood, Urban, and Regional.	2.0–15	≥1.0	≥10	*See* Table E–1.
	Micro	2.0–7.0			≤50 for near-road micro-scale.
NO_2 [2 3 4]	Middle, Neighborhood, Urban, and Regional.	2.0–15	≥1.0	≥10	*See* Table E–1.
PAMS [2 3 4] Ozone precursors	Neighborhood and Urban	2.0–15	≥1.0	≥10	*See* Table E–1.
PM, Pb [2 3 4 7]	Micro	2.0–7.0			
	Middle, Neighborhood, Urban and Regional.	2.0–15	≥2.0 (horizontal distance only)	≥10	*See* Figure E–1.

N/A—Not applicable.

[1] When a probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on the roof.

[2] Should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline.

[3] Distance from sampler or probe inlet to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler or probe inlet. Sites not meeting this criterion may be classified as microscale or middle scale (*see* paragraphs 2.3(a) and 2.3(c)).

[4] Must have unrestricted airflow in a continuous arc of at least 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall for street canyon monitoring.

[5] The probe or sampler should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source emission point(s), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[6] For microscale CO monitoring sites, the probe must be ≥10 meters from a street intersection and preferably at a midblock location.

[7] Collocated monitor inlets must be within 4.0 meters of each other and at least 2.0 meters apart for flow rates greater than 200 liters/min or at least 1.0 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference, unless a waiver has been granted by the Regional Administrator pursuant to paragraph 3.3.4.2(c) of appendix A of part 58. For $PM_{2.5}$, collocated monitor inlet heights should be within 1.0 meter of each other vertically.

[8] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

[9] See section 1.2 of appendix D for definitions of monitoring scales.

3. Open Path Analyzers

3.1 Horizontal and Vertical Placement

(a) For all O_3 and SO_2 monitoring sites and for neighborhood or larger spatial scale NO_2, and CO sites, at least 80 percent of the monitoring path must be located greater than or equal 2.0 meters and less than or equal to 15 meters above ground level.

(b) Middle scale CO and NO_2 sites must have monitoring paths greater than or equal 2.0 meters and less than or equal to 15 meters above ground level.

(c) Microscale near-road monitoring sites are required to have monitoring paths greater than or equal 2.0 meters and less than or equal to 7.0 meters above ground level.

(d) For microscale carbon monoxide monitors that are being used to measure concentrations near roadways, the monitoring path must be greater than or equal 2.0 meters and less than or equal to 7.0 meters above ground level. If the microscale carbon monoxide monitors measuring concentrations near roadways are in downtown areas or urban street canyons, the monitoring path must be greater than or equal 2.5 meters and less than or equal to 3.5 meters above ground level and at least 90

percent of the monitoring path must be at least 1.0 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If a significant portion of the monitoring path is located near the side of a building or wall, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

3.2 Spacing From Minor Sources

(a) It is important to understand the monitoring objective for a particular site in order to interpret this requirement. Local minor sources of a primary pollutant, such as SO_2 can cause high concentrations of that particular pollutant at a monitoring site. If the objective for that monitoring site is to investigate these local primary pollutant emissions, then the site will likely be properly located nearby. This type of monitoring site would, in all likelihood, be a microscale type of monitoring site. If a monitoring site is to be used to determine air quality over a much larger area, such as a neighborhood or city, a monitoring agency should avoid placing a monitoring path near local, minor sources, because a plume from a local minor source should not be allowed to inappropriately impact the air quality data collected at a site.

(b) Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of O_3 in the vicinity of monitoring paths for O_3. To minimize these potential interferences from nearby minor sources, at least 90 percent of the monitoring path should be at a distance from furnace or incineration flues or other minor sources of SO_2 or NO. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel.

3.3 Spacing From Obstructions

(a) Obstacles may scavenge SO_2, O_3, or NO_2, and can act to restrict airflow for any pollutant. To avoid this interference, at least 90 percent of the monitoring path must have unrestricted airflow and should be located at a distance from obstacles. The horizontal distance from the obstacle to the monitoring path must be at least twice the height that the obstacle protrudes above the monitoring path. An obstacle that does not meet the minimum distance requirement is considered an obstruction that restricts airflow to the monitoring path. The EPA does not generally consider objects or obstacles such as flag poles or site towers used for NOy convertors and meteorological sensors, etc. to be deemed obstructions.

(b) A monitoring path located near or along a vertical wall is undesirable because air moving along the wall may be subject to removal mechanisms. At least 90 percent of the monitoring path for open path analyzers must have unrestricted airflow with no obstructions (as defined in paragraph (a) of this section) in a continuous arc of at least 270 degrees. An unobstructed continuous arc of 180 degrees is allowable when the applicable network design criteria specified in appendix D of this part require monitoring in street canyons and the monitoring path is located on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential.

(c) Special consideration must be given to the use of open path analyzers given their inherent potential sensitivity to certain types of interferences and optical obstructions. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will negatively affect the ability of the open path analyzer to continuously measure pollutant concentrations. Transient, but significant obscuration of especially longer measurement paths, could occur as a result of certain meteorological conditions (*e.g.,* heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (*e.g.,* shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be compromised. For instance, if heavy fog or high particulate levels are coincident with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollution concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high, overall valid data capture rate.

(d) A sampling station with a monitoring path located closer to an obstacle than required by the criteria in this section should be classified as middle scale or microscale, rather than neighborhood or urban scale, since the measurements from such a station would more closely represent these smaller scales.

(e) For near-road monitoring stations, the monitoring path shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitoring path, between the monitoring path and the outside nearest edge of the traffic lanes of the target road segment.

3.4 Spacing From Trees

(a) Trees can provide surfaces for SO_2, O_3, or NO_2 adsorption or reactions. Trees can also act as obstructions in locations where the trees are located between the air pollutant sources or source areas and the monitoring site, and where the trees are of a sufficient height and leaf canopy density to interfere with the normal airflow around the monitoring path. To reduce this possible interference/obstruction, at least 90 percent of the monitoring path should be 20 meters or more from the drip line of trees and must be at least 10 meters from the drip line of trees. If a tree or group of trees could be considered an obstacle, the monitoring path must meet the distance requirements of section 3.3 of this appendix.

(b) The scavenging effect of trees is greater for O_3 than for other criteria pollutants. Monitoring agencies must take steps to consider the impact of trees on ozone monitoring sites and take steps to avoid this problem.

(c) Beginning January 1, 2024, microscale sites of any air pollutant shall have no trees or shrubs located at or above the line-of-sight fetch between the monitoring path and the source under investigation, *e.g.,* a roadway or a stationary source.

3.5 Spacing from Roadways

TABLE E–4 OF SECTION 3.5 OF APPENDIX E—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND MONITORING PATHS FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE (O**3**) AND OXIDES OF NITROGEN (NO, NO**2**, NO**X**, NO**y**)

Roadway average daily traffic, vehicles per day	Minimum distance [1] [3] (meters)	Minimum distance [1] [2] [3] (meters)
≤1,000	10	10
10,000	10	20
15,000	20	30
20,000	30	40
40,000	50	60
70,000	100	100
≥110,000	250	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] Applicable for ozone open path monitors whose placement was not approved as of December 18, 2006.

[3] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

3.5.1 Spacing for Ozone Monitoring Paths

In siting an O_3 open path analyzer, it is important to minimize destructive interferences form sources of NO, since NO readily reacts with O_3. Table E–4 of this appendix provides the required minimum separation distances between a roadway and at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A monitoring site with a monitoring path located closer to a roadway than allowed by the Table E–4 requirements should be classified as microscale or middle scale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent these smaller scales. The monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For locations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference from automobile emissions. Therefore, this

calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from Table E–4 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

3.5.2 Spacing for Carbon Monoxide Monitoring Paths

(a) Near-road microscale CO monitoring sites, including those located in downtown areas, urban street canyons, and other near-road locations such as those adjacent to highly trafficked roads, are intended to provide a measurement of the influence of the immediate source on the pollution exposure on the adjacent area.

(b) Microscale CO monitoring paths in downtown areas or urban street canyon locations shall be located a minimum distance of 2.0 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane.

(c) Microscale CO monitoring paths in downtown areas or urban street canyon locations shall be located at least 10 meters from an intersection, preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections.

(d) Neighborhood scale CO monitoring paths in downtown areas or urban street canyon locations shall be located according to the requirements in Table E–5 of this appendix.

TABLE E–5 SECTION 3.5.2 OF APPENDIX E—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND MONITORING PATHS FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE

Roadway average daily traffic, vehicles per day	Minimum distance [1] [2] (meters)
≤10,000	10
15,000	25
20,000	45
30,000	80
40,000	115
50,000	135
≥60,000	150

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

3.5.3 Spacing for Nitrogen Dioxide (NO_2) Monitoring Paths

(a) In siting near-road NO_2 monitors as required in section 4.3.2 of appendix D of this part, the monitoring path shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment.

(b) In siting NO_2 open path monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E–5 of this appendix provides the required minimum separation distances between a roadway and at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A site with a monitoring path located closer to a roadway than allowed by the Table E–4 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale. The monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For locations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference form automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from Table E–5 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

3.6 Cumulative Interferences on a Monitoring Path

The cumulative length or portion of a monitoring path that is affected by minor sources, trees, or roadways must not exceed 10 percent of the total monitoring path length.

3.7 Maximum Monitoring Path Length

The monitoring path length must not exceed 1.0 kilometer for open path analyzers in neighborhood, urban, or regional scale. For middle scale monitoring sites, the monitoring path length must not exceed 300 meters. In areas subject to frequent periods of dust, fog, rain, or snow, consideration should be given to a shortened monitoring path length to minimize loss of monitoring data due to these temporary optical obstructions. For certain ambient air monitoring scenarios using open path analyzers, shorter path lengths may be needed in order to ensure that the monitoring site meets the objectives and spatial scales defined in appendix D to this part. The Regional Administrator may require shorter path lengths, as needed on an individual basis, to ensure that the SLAMS sites meet the appendix D requirements. Likewise, the Administrator may specify the maximum path length used at NCore monitoring sites.

3.8 Summary

Table E–6 of this appendix presents a summary of the general requirements for monitoring path siting criteria with respect to distances and heights. Table E–6 requires different elevation distances above the ground for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For source oriented and near-road monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a monitoring path for monitoring more than one pollutant.

TABLE E–6 SECTION 3.8 OF APPENDIX E—SUMMARY OF MONITORING PATH SITING CRITERIA

Pollutant	Maximum monitoring path length [9] [10]	Height from ground to 80% of monitoring path [1] [8] (meters)	Horizontal or vertical distance from supporting structures [2] to 90% of monitoring path [1] [8] (meters)	Distance from trees to 90% of monitoring path [1] [8] (meters)	Distance from roadways to monitoring path [1] [8] (meters)
SO_2 [3] [4] [5] [6]	<= 300 m for Middle	2.0–15	≥1.0	≥10	N/A.
	<= 1.0 km for Neighborhood, Urban, and Regional				
CO [4] [5] [7]	<= 300 m for Micro [downtown or street canyon sites].	2.5–3.5	≥1.0	≥10	2.0–10 for downtown areas or street canyon microscale.
	<= 300 m for Micro [Near-Road sites].	2.0–7.0			≤50 for near-road microscale.

TABLE E–6 SECTION 3.8 OF APPENDIX E—SUMMARY OF MONITORING PATH SITING CRITERIA—Continued

Pollutant	Maximum monitoring path length [9] [10]	Height from ground to 80% of monitoring path [1] [8] (meters)	Horizontal or vertical distance from supporting structures [2] to 90% of monitoring path [1] [8] (meters)	Distance from trees to 90% of monitoring path [1] [8] (meters)	Distance from roadways to monitoring path [1] [8] (meters)
	<= 300 m for Middle	2.0–15			*See* Table E–5 of this appendix for middle and neighborhood scales.
	<= 1.0 km for Neighborhood.				
O_3 [3] [4] [5]	<= 300 m for Middle.				
	<= 1.0 km for Neighborhood, Urban, and Regional.	2.0–15	≥1.0	≥10	*See* Table E–4.
NO_2 [3] [4] [5]	Between 50 m–300 m for Micro (Near-Road).	2.0–7.0			≤50 for near-road micro-scale.
	<= 300 m for Middle		≥1.0	≥10	
	<= 1.0 km for Neighborhood, Urban, and Regional.	2.0–15			*See* Table E–4.
PAMS [3] [4] [5] Ozone precursors	<= 1.0 km for Neighborhood and Urban.	2.0–15	≥1.0	≥10	*See* Table E–4.

N/A—Not applicable.

[1] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale NO_2 monitoring, and all applicable scales for monitoring SO_2, O_3, and O_3 precursors.

[2] When the monitoring path is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3] At least 90 percent of the monitoring path should be greater than 20 meters from the dripline of tree(s) and must be 10-meters from the dripline.

[4] Distance from 90 percent of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the monitoring path. Sites not meeting this criterion may be classified as microscale or middle scale (*see* text).

[5] Must have unrestricted airflow 270 degrees around at least 90 percent of the monitoring path; 180 degrees if the monitoring path is adjacent to the side of a building or a wall for street canyon monitoring.

[6] The monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[7] For microscale CO monitoring sites, the monitoring path must be ≥10. meters from a street intersection and preferably at a midblock location.

[8] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

[9] See section 1.2 of appendix D for definitions of monitoring scales.

[10] See section 3.7 of this appendix.

4. Waiver Provisions

Most sampling probes or monitors can be located so that they meet the requirements of this appendix. New sites, with rare exceptions, can be located within the limits of this appendix. However, some existing sites may not meet these requirements and may still produce useful data for some purposes. The EPA will consider a written request from the State, or where applicable local, agency to waive one or more siting criteria for some monitoring sites providing that the State or their designee can adequately demonstrate the need (purpose) for monitoring or establishing a monitoring site at that location.

4.1 For a proposed new site, a waiver may be granted only if both the following criteria are met:

4.1.1 The proposed new site can be demonstrated to be as representative of the monitoring area as it would be if the siting criteria were being met.

4.1.2 The monitor or probe cannot reasonably be located so as to meet the siting criteria because of physical constraints (*e.g.,* inability to locate the required type of site the necessary distance from roadways or obstructions).

4.2 For an existing site, a waiver may be granted if either the criterion in section 4.1.1 or the criterion in 4.1.2 of this appendix is met.

4.3 Cost benefits, historical trends, and other factors may be used to add support to the criteria in sections 4.1.1 and 4.1.2 of this appendix; however, by themselves, they will not be acceptable reasons for the EPA to grant a waiver. Written requests for waivers must be submitted to the Regional Administrator. Granted waivers must be renewed minimally every 5 years and ideally as part of the network assessment as defined in § 58.10(d). The approval date of the waiver must be documented in the annual monitoring network plan to support the requirements of § 58.10(a)(1) and 58.10(b)(10).

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■ 31. Revise appendix G to part 58 to read as follows:

Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting

1. General Information
2. Reporting Requirements
3. Data Handling

1. General Information

1.1 *AQI Overview.* The AQI is a tool that simplifies reporting air quality to the public in a nationally uniform and easy to understand manner. The AQI converts concentrations of pollutants, for which the EPA has established a national ambient air quality standard (NAAQS), into a uniform scale from 0–500. These pollutants are ozone (O_3), particulate matter ($PM_{2.5}$, PM_{10}), carbon monoxide (CO), sulfur dioxide (SO_2), and nitrogen dioxide (NO_2). The scale of the index is divided into general categories that are associated with health messages.

2. Reporting Requirements

2.1 *Applicability.* The AQI must be reported daily for a metropolitan statistical area (MSA) with a population over 350,000. When it is useful and possible, it is recommended, but not required for an area to report a sub-daily AQI as well.

2.2 *Contents of AQI Report.*

2.2.1 *Content of AQI Report Requirements.* An AQI report must contain the following:

a. The reporting area(s) (the MSA or subdivision of the MSA).

b. The reporting period (the day for which the AQI is reported).

c. The main pollutant (the pollutant with the highest index value).

d. The AQI (the highest index value).

e. The category descriptor and index value associated with the AQI and, if choosing to report in a color format, the associated color. Use only the following descriptors and colors for the six AQI categories:

TABLE 1 TO SECTION 2 OF APPENDIX G—AQI CATEGORIES

For this AQI	Use this descriptor	And this color [1]
0 to 50	"Good"	Green.
51 to 100	"Moderate"	Yellow.
101 to 150	"Unhealthy for Sensitive Groups"	Orange.
151 to 200	"Unhealthy"	Red.
201 to 300	"Very Unhealthy"	Purple.
301 and above	"Hazardous"	Maroon[1].

[1]Specific color definitions can be found in the most recent reporting guidance (Technical Assistance Document for the Reporting of Daily Air Quality), which can be found at *https://www.airnow.gov/publications/air-quality-index/technical-assistance-document-for-reporting-the-daily-aqi/.*

f. The pollutant specific sensitive groups for any reported index value greater than 100. The sensitive groups for each pollutant are identified as part of the periodic review of the air quality criteria and the NAAQS. For convenience, the EPA lists the relevant groups for each pollutant in the most recent reporting guidance (Technical Assistance Document for the Reporting of Daily Air Quality), which can be found at *https://www.airnow.gov/publications/air-quality-index/technical-assistance-document-for-reporting-the-daily-aqi/.*

2.2.2 *Contents of AQI Report When Applicable.* When appropriate, the AQI report may also contain the following, but such information is not required:

a. Appropriate health and cautionary statements.

b. The name and index value for other pollutants, particularly those with an index value greater than 100.

c. The index values for sub-areas of your MSA.

d. Causes for unusually high AQI values.

e. Pollutant concentrations.

f. Generally, the AQI report applies to an area's MSA only. However, if a significant air quality problem exists (AQI greater than 100) in areas significantly impacted by the MSA but not in it (for example, O_3 concentrations are often highest downwind and outside an urban area), the report should identify these areas and report the AQI for these areas as well.

2.3. *Communication, Timing, and Frequency of AQI Report.* The daily AQI must be reported 7 days per week and made available via website or other means of public access. The daily AQI report represents the air quality for the previous day. Exceptions to this requirement are in section 2.4 of this appendix.

a. Reporting the AQI sub-daily is recommended, but not required, to provide more timely air quality information to the public for making health-protective decisions.

b. Submitting hourly data in real-time to the EPA's AirNow (or future analogous) system is recommended, but not required, and assists the EPA in providing timely air quality information to the public for making health-protective decisions.

c. Submitting hourly data for appropriate monitors (referenced in section 3.2 of this appendix) satisfies the daily AQI reporting requirement because the AirNow system makes daily and sub-daily AQI reports widely available through its website and other communication tools.

d. Forecasting the daily AQI provides timely air quality information to the public and is recommended but not required. Sub-daily forecasts are also recommended, especially when air quality is expected to vary substantially throughout the day, like during wildfires. Long-term (multi-day) forecasts can also be made available when useful.

2.4. *Exceptions to Reporting Requirements.*

a. If the index value for a particular pollutant remains below 50 for a season or year, then it may be excluded from the calculation of the AQI in section 3 of this appendix.

b. If all index values remain below 50 for a year, then the AQI may be reported at the discretion of the reporting agency. In subsequent years, if pollutant levels rise to where the AQI would be above 50, then the AQI must be reported as required in section 2 of this appendix.

c. As previously mentioned in section 2.3 of this appendix, submitting hourly data in real-time from appropriate monitors (referenced in section 3.2 of this appendix) to the EPA's AirNow (or future analogous) system satisfies the daily AQI reporting requirement.

3. Data Handling.

3.1 *Relationship of AQI and pollutant concentrations.* For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. As appropriate, the AQI is associated with the NAAQS for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (*i.e.,* averaging time of 24-hours or less) for each pollutant. The index value of 50 is associated with the numerical level of the annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on the potential for increasingly serious health effects to occur following exposure and increasing proportions of the population that are likely to be affected. The reported AQI corresponds to the pollutant with the highest calculated AQI. For the purposes of reporting the AQI, the sub-indexes for PM_{10} and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the ''main'' pollutant for that day.

3.2 *Monitors Used for AQI Reporting.* Concentration data from State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 must be used for each pollutant except PM. For PM, calculate and report the AQI on days for which air quality data has been measured (*e.g.,* from continuous $PM_{2.5}$ monitors required in appendix D to this part). PM measurements may be used from monitors that are not reference or equivalent methods (for example, continuous PM_{10} or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced here:

Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S. Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/B–02–002, November 2002).

3.3 *AQI Forecast.* The AQI can be forecasted at least 24-hours in advance using the most accurate and reasonable procedures considering meteorology, topography, availability of data, and forecasting expertise. The guidance document, ''Guidelines for Developing an Air Quality (Ozone and $PM_{2.5}$) Forecasting Program,'' can be found at *https://www.airnow.gov/publications/weathercasters/guidelines-developing-air-quality-forecasting-program/.*

3.4 *Calculation and Equations.*

a. The AQI is the highest value calculated for each pollutant as follows:

i. Identify the highest concentration among all of the monitors within each reporting area and truncate as follows:

(A) Ozone—truncate to 3 decimal places
$PM_{2.5}$—truncate to 1 decimal place
PM_{10}—truncate to integer
CO—truncate to 1 decimal place
SO_2—truncate to integer
NO_2—truncate to integer

(B) [Reserved]

ii. Using table 2 to this appendix, find the two breakpoints that contain the concentration.

iii. Using equation 1 to this appendix, calculate the index.

iv. Round the index to the nearest integer.

TABLE 2 TO SECTION 3.4 OF APPENDIX G—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (µg/m^3) 24-hour	PM_{10} (µg/m^3) 24-hour	CO (ppm) 8-hour	SO_2 (ppb) 1-hour	NO_2 (ppb) 1-hour	AQI	Category
0.000–0.054	.....	0.0–9.0	0–54	0.0–4.4	0–35	0–53	0–50	Good.
0.055–0.070	.....	9.1–35.4	55–154	4.5–9.4	36–75	54–100	51–100	Moderate.
0.071–0.085	0.125–0.164	35.5–55.4	155–254	9.5–12.4	76–185	101–360	101–150	Unhealthy for Sensitive Groups.
0.086–0.105	0.165–0.204	55.5–125.4	255–354	12.5–15.4	[3]186–304	361–649	151–200	Unhealthy.
0.106–0.200	0.205–0.404	125.5—225.4	355–424	15.5–30.4	[3]305–604	650–1249	201–300	Very Unhealthy.

TABLE 2 TO SECTION 3.4 OF APPENDIX G—BREAKPOINTS FOR THE AQI—Continued

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (μg/m³) 24-hour	PM_{10} (μg/m³) 24-hour	CO (ppm) 8-hour	SO_2 (ppb) 1-hour	NO_2 (ppb) 1-hour	AQI	Category
0.201 – ([2])	0.405+	225.5+	425+	30.5+	[3] 605+	1250+	301+	[4] Hazardous.

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.
[2] 8-hour O_3 concentrations do not define higher AQI values (≤301). AQI values > 301 are calculated with 1-hour O_3 concentrations.
[3] 1-hr SO_2 concentrations do not define higher AQI values (≥200). AQI values of 200 or greater are calculated with 24-hour SO_2 concentration.
[4] AQI values between breakpoints are calculated using equation 1 to this appendix. For AQI values in the hazardous category, AQI values greater than 500 should be calculated using equation 1 and the concentration specified for the AQI value of 500. The AQI value of 500 are as follows: O_3 1-hour—0.604 ppm; $PM_{2.5}$ 24-hour—325.4 μg/m³; PM_{10} 24-hour—604 μg/m³; CO ppm—50.4 ppm; SO_2 1-hour—1004 ppb; and NO_2 1-hour—2049 ppb.

b. If the concentration is equal to a breakpoint, then the index is equal to the corresponding index value in table 2 to this appendix. However, equation 1 to this appendix can still be used. The results will be equal. If the concentration is between two breakpoints, then calculate the index of that pollutant with equation 1. It should also be noted that in some areas, the AQI based on 1-hour O_3 will be more precautionary than using 8-hour values (*see* footnote 1 to table 2). In these cases, the 1-hour values as well as 8-hour values may be used to calculate index values and then use the maximum index value as the AQI for O_3.

Equation 1 to Appendix G to Part 58

$$I_p = \frac{I_{Hi} - I_{Lo}}{BP_{Hi} - BP_{Lo}}\left(C_p - BP_{Lo}\right) + I_{Lo}$$

Where:
I_p = the index value for pollutant$_p$.
C_p = the truncated concentration of pollutant$_p$.
BP_{Hi} = the breakpoint that is greater than or equal to C_p.
BP_{Lo} = the breakpoint that is less than or equal to C_p.
I_{Hi} = the AQI value corresponding to BP_{Hi}.
I_{lo} = the AQI value corresponding to BP_{Lo}.

c. If the concentration is larger than the highest breakpoint in table 2 to this appendix then the last two breakpoints in table 2 may be used when equation 1 to this appendix is applied.
Example:

d. Using table 2 and equation 1 to this appendix, calculate the index value for each of the pollutants measured and select the one that produces the highest index value for the AQI. For example, if a PM_{10} value of 210 μg/m³ is observed, a 1-hour O_3 value of 0.156 ppm, and an 8-hour O_3 value of 0.130 ppm, then do this:

i. Find the breakpoints for PM_{10} at 210 μg/m³ as 155 μg/m³ and 254 μg/m³, corresponding to index values 101 and 150;

ii. Find the breakpoints for 1-hour O_3 at 0.156 ppm as 0.125 ppm and 0.164 ppm, corresponding to index values 101 and 150;

iii. Find the breakpoints for 8-hour O_3 at 0.130 ppm as 0.116 ppm and 0.374 ppm, corresponding to index values 201 and 300;

iv. Apply equation 21 to this appendix for 210 μg/m³, PM_{10}:

Equation 2 to Appendix G to Part 58

$$\frac{150 - 101}{254 - 155}(210 - 155) + 101 = 128$$

v. Apply equation 3 to this appendix for 0.156 ppm, 1-hour O_3:

Equation 3 to Appendix G to Part 58

$$\frac{150 - 101}{0.164 - 0.125}(0.156 - 0.125) + 101 = 140$$

vi. Apply equation 4 to this appendix for 0.130 ppm, 8-hour O_3:

Equation 4 to Appendix G to Part 58

$$\frac{300 - 201}{0.374 - 0.116}(0.130 - 0.116) + 201 = 206$$

vii. Find the maximum, 206. This is the AQI. A minimal AQI report could read: ''Today, the AQI for my city is 206, which is Very Unhealthy, due to ozone.'' It would then reference the associated sensitive groups.

[FR Doc. 2024–02637 Filed 3–5–24; 8:45 am]

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Part IV

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2017–0664; FRL–5925.1–01–OAR]

RIN 2060–AV58

National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is finalizing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Taconite Iron Ore Processing. Specifically, the EPA is finalizing maximum achievable control technology (MACT) standards for mercury (Hg) and establishing revised emission standards for hydrogen chloride (HCl) and hydrogen fluoride (HF). This final action ensures that emissions of all hazardous air pollutants (HAP) emitted from the Taconite Iron Ore Processing source category are regulated.

DATES: This final rule is effective March 6, 2024. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register (FR) as of March 6, 2024. The incorporation by reference of certain other material listed in the rule was approved by the Director of the Federal Register as of October 26, 2020.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2017–0664. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and is publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov/*or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact David Putney, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–2016; email address: *putney.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. Throughout this document the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACI activated carbon injection
BTF beyond-the-floor
CAA Clean Air Act
CBI Confidential Business Information
CEMS continuous emission monitoring system
CFR Code of Federal Regulations
D.C. Circuit United States Court of Appeals for the District of Columbia Circuit
DSI dry sorbent injection
EJ environmental justice
EPA Environmental Protection Agency
ESP electrostatic precipitator
FR Federal Register
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HF hydrogen fluoride
Hg mercury
ICR information collection request
km kilometer
LEAN Louisiana Environmental Action Network
lb/LT pounds of HAP (*i.e.,* Hg, HCl, or HF) emitted per long ton of pellets produced
MACT maximum achievable control technology
MWh/yr megawatt-hours per year
MPCA Minnesota Pollution Control Agency
NAICS North American Industry Classification System
NESHAP National Emission Standards for Hazardous Air Pollutants
ng/g nanograms per gram
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PM particulate matter
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
RTR residual risk and technology review
tpy tons per year
UPL upper prediction limit
µg/Nm3 microgram per normal cubic meter
UMRA Unfunded Mandates Reform Act
VCS voluntary consensus standards

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source category that is the

subject of this final rule. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this final action is likely to affect. The final standards are directly applicable to the affected sources. Federal, state, local, and Tribal government entities are not affected by this final action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576; July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA–450/3–91–030; July 1992), the Taconite Iron Ore Processing source category includes any facility engaged in separating and concentrating iron ore from taconite, a low-grade iron ore to produce taconite pellets. The source category includes, but is not limited to, the following processes: liberation of the iron ore by wet or dry crushing and grinding in gyratory crushers, cone crushers, rod mills, and ball mills; pelletizing by wet tumbling with a balling drum or balling disc; induration using a straight grate or grate kiln indurating furnace; and finished pellet handling.

TABLE 1—NESHAP AND SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Source category	NESHAP	NAICS code [1]
Taconite Iron Ore Processing	40 CFR part 63, subpart RRRRR	21221

[1] North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/taconite-iron-ore-processing-national-emission-standards-hazardous.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) by May 6, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

In the *Louisiana Environmental Action Network* v. *EPA* (''*LEAN*'') decision issued on April 21, 2020, the D.C. Circuit held that the EPA has an obligation to address regulatory gaps, such as missing standards for HAP known to be emitted from a major source category, when the Agency conducts the 8-year technology review required by CAA section 112(d)(6).[1] Emissions data collected from the exhaust stacks of existing taconite indurating furnaces indicate that Hg is emitted from the source category. However, Hg emissions from the Taconite Iron Ore Processing source category are not regulated under the existing Taconite Iron Ore Processing NESHAP. To meet the EPA's obligations under CAA section 112(d)(6), in this action, the EPA is establishing new standards for Hg emissions from the Taconite Iron Ore Processing source category that reflect MACT for Hg emitted from taconite indurating furnaces, pursuant to CAA sections 112(d)(2) and (3).

The EPA is also finalizing revised standards for HCl and HF pursuant to CAA section 112(d)(6). CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years.

B. What is the source category and how does the current NESHAP regulate its HAP emissions?

The Taconite Iron Ore Processing NESHAP (codified at 40 Code of Federal Regulations (CFR) part 63, subpart RRRRR) applies to each new or existing ore crushing and handling operation, ore dryer, pellet indurating furnace, and finished pellet handling operation at a taconite iron ore processing plant that is (or is part of) a major source of HAP emissions. Taconite iron ore processing plants separate and concentrate iron ore from taconite, a low-grade iron ore containing 20- to 25-percent iron, and produce taconite pellets, which are 60- to 65-percent iron. The current NESHAP includes particulate matter (PM) limits that, prior to this final action, served as a surrogate for particulate metal HAP, HCl, and HF emissions. The existing PM emissions limits were summarized in table 2 of the proposal (see 88 FR 30917; May 15, 2023). The current NESHAP does not presently include standards for Hg emissions.

There are currently eight taconite iron ore processing plants in the United States: six plants are located in Minnesota and two are located in Michigan. This includes the Empire Mining facility in Michigan, which maintains an air quality permit to operate, but has been indefinitely idled since 2016 and is therefore not included

[1] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020) (''*LEAN*'').

in any analyses (*e.g.,* estimates of emissions or cost impacts) associated with this final rulemaking.

C. What changes did we propose for the Taconite Iron Ore Processing source category?

On May 15, 2023, the EPA published a proposal in the **Federal Register** to set MACT standards for Hg emissions from indurating furnaces in the source category and to revise the existing emission standards for HCl and HF for indurating furnaces. The PM emission limits in the current NESHAP will continue to serve as surrogate for particulate metal HAP (*e.g.,* nickel and arsenic). The EPA proposed that compliance with the emission standards for Hg, HCl, and HF be demonstrated through operating limits, monitoring, and performance testing. We also proposed minor changes to the electronic reporting requirements found in 40 CFR 63.9641(c) and 40 CFR 63.9641(f)(3) to reflect new procedures for reporting CBI that included an email address for owners and operators to electronically submit compliance reports containing CBI to the Office of Air Quality Planning and Standards (OAQPS) CBI Office. Finally, we requested comment on our evaluation that the addition of 1-bromopropane (1–BP) to the CAA section 112 HAP list would not impact the Taconite Iron Ore Processing NESHAP because, based on our knowledge of the source category and available emissions data, 1–BP is not emitted from this source category.

III. What is the rationale for our final decisions and amendments for the Taconite Iron Ore Processing source category?

For each issue, this section provides a description of what we proposed and what we are finalizing, a summary of key comments and responses, and the EPA's rationale for the final decisions and amendments. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the document, *Summary of Public Comments and Responses for Proposed Amendments to the National Emission Standards for Hazardous Air Pollutants for Taconite Iron Ore Processing,* which is available in the docket for this action.

A. MACT Standards for Mercury

1. What did we propose for the Taconite Iron Ore Processing source category?

As described in the May 15, 2023, proposal (88 FR 30917), we proposed MACT standards for Hg for new and existing indurating furnaces that reflected the MACT floor level of control, based on the 99-percent upper prediction limit (UPL), of 1.4×10^{-5} pounds of Hg emitted per long ton of taconite pellets produced (lb/LT) for existing sources and 3.1×10^{-6} lb/LT for new sources. We also proposed an emissions averaging compliance alternative that would allow taconite iron ore processing facilities with more than one existing indurating furnace to comply with a Hg emissions limit of 1.26×10^{-5} lb/LT by averaging emissions on a production-weighted basis for two or more existing indurating furnaces located at the same facility. In the proposal, we explained that the emissions averaging compliance alternative reflected a 10 percent adjustment factor to the proposed MACT floor standard and that we expected this 10 percent adjustment factor would result in Hg reductions greater than those achieved by compliance with the MACT floor on a unit-by-unit basis. We proposed that compliance with the Hg MACT standards would be demonstrated through initial and periodic performance testing (completed at least twice per 5-year permit term), establishing operating limits for each control device used to comply with the Hg standards, and installing and operating continuous parameter monitoring systems (CPMS) to ensure continuous compliance with the Hg standards.

For the proposal, in addition to calculating the MACT floor, pursuant to CAA section 112(d)(2), we also assessed more stringent ''beyond-the-floor'' (BTF) regulatory options for the Hg MACT standards. As discussed in the proposal (88 FR 30923), unlike the MACT floor's minimum stringency requirements, the EPA must examine various impacts of the more stringent BTF regulatory options in determining whether MACT standards are to reflect BTF requirements. These impacts include the cost of achieving additional emissions reductions beyond those achieved by the MACT floor level of control, any non-air quality health and environmental impacts that would result from imposing controls BTF, and energy requirements of such BTF measures. If the EPA concludes that the more stringent regulatory options have unreasonable impacts, the EPA selects the MACT floor level of control as MACT. However, if the EPA concludes that impacts associated with BTF levels of control are reasonable in light of additional HAP emissions reductions achieved, then the EPA selects those BTF levels as MACT.

We considered BTF regulatory options that were 10, 20, 30, and 40 percent more stringent than the MACT floor and calculated the capital and annual costs as well as secondary impacts associated with each option. For a detailed discussion of our analysis of emissions reductions and potential secondary impacts developed for the proposal, please see the memorandum, *Development of Impacts for the Proposed Amendments to the NESHAP for Taconite Iron Ore Processing,* which is available in the docket for this action. We proposed that requiring new or existing furnaces to meet BTF emission limits was not reasonable based on the estimated capital and operating costs and cost-effectiveness.

2. What comments did we receive on the proposed Hg MACT standards, and what are our responses?

Comment: Industry commenters provided data that they indicated corrected the Hg stack test data submitted in response to the CAA section 114 Information Collection Request (ICR) sent to the taconite facilities in 2022 for the Tilden, UTAC, Keetac, and Hibbing facilities that were used when calculating the baseline emissions, the MACT floor standards, and the emission reductions. The commenters indicated that the error in the Keetac emissions data resulted in an overestimate of both the baseline emissions and the estimated emission reductions that could be achieved if the proposed Hg standards were adopted.

Response: In response to these comments and revised data provided, the EPA reviewed the Hg emissions data that we used in the proposal to calculate baseline Hg emissions. At proposal we estimated total baseline Hg emissions were 1,010 pounds per year. The EPA confirmed that errors were present in the Hg emissions data used to calculate the baseline emissions. We revised the emissions data as appropriate based on the emissions data provided by industry commenters and recalculated the baseline emissions, MACT floor emission limits, emission reductions, and estimated capital and annual costs accordingly for the final rule. The updates to the emissions data did not impact the MACT floor limit for existing sources but did decrease the baseline emissions and the expected Hg emissions reductions for existing sources. The updates to the emissions data changed the Hg standard for new sources from 3.1×10^{-6} lb/LT to 2.6×10^{-6} lb/LT. The updated baseline Hg emissions for the final rule are estimated to be 751 pounds per year (0.38 tons per year (tpy)). We estimate

that unit-by-unit compliance with the final MACT floor limit will result in a reduction of 232 pounds of Hg emissions per year and a reduction of 247 pounds per year of Hg emissions if all facilities with more than one existing taconite furnace elect to demonstrate compliance through the emissions averaging compliance alternative. Our analysis is presented in detail in the memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing.* The updated emissions data used in the revised calculations for the final rule are summarized in a separate memorandum, *Final Emissions Data Collected in 2022 for Indurating Furnaces Located at Taconite Iron Ore Processing Plants.* These documents are available in the docket for this action.

Comment: One commenter recommended the proposed limit for the emissions averaging compliance alternative for existing sources should have the same number of significant figures as the MACT floor limit. Instead of 1.26×10^{-5} lb/LT, the limit for the emissions averaging compliance alternative for existing sources would be rounded up to 1.3×10^{-5} lb/LT.

Response: The EPA agrees with the commenter that the Hg emission limit for the emissions averaging compliance option should have only two significant figures. The limit cannot have more significant figures than Hg MACT floor from which it was derived, which has only two significant figures. As recommended by commenters, the Hg emission limit in the final rule is revised to 1.3×10^{-5} lb/LT so that the limit for the emissions averaging compliance alternative has the same number of significant figures as the other Hg limits finalized in this rulemaking.

We estimate that the final Hg emissions averaging compliance alternative will reduce Hg emissions by 247 pounds per year, if Hibbing and Minntac elect to demonstrate compliance through the emissions averaging compliance alternative by each facility installing mercury controls on two furnaces and averaging the emissions across all furnaces located at their facility. We expect that, should Hibbing and Minntac elect to demonstrate compliance through the emissions averaging compliance alternative, the Hg reductions would still be greater than the reductions we anticipate would be achieved through unit-by-unit compliance with the MACT floor level of control. For additional details, please refer to section IV.A.1 of the proposal preamble (88 FR 30925). More information on the final Hg standards, including the detailed cost estimates for the Hg emissions averaging compliance alternative, may be found in the memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing,* which is available in the docket for this action.

Comment: Commenters recommended that the proposed 40 CFR 63.9621(d)(4) and 63.9631(j) be revised to allow the mass of taconite pellets produced to be determined indirectly through calculation based on industry standards. They noted that pellet mass is measured prior to offsite shipment and later ''trued-up'' at the end of each month.

Response: The EPA agrees that taconite pellet production can be determined indirectly through calculation using bulk density and volume measurements. We have revised the language in 40 CFR 63.9621(d)(4) and 63.9631(j) to allow the weight of taconite pellets produced to be determined either by direct measurement using weigh hoppers, belt weigh feeders, or weighed quantities in shipments, or calculated using the bulk density and volume measurements.

Comment: Industry commenters stated that the capital and operating costs for Hg controls were underestimated in the proposal and that the estimated capital costs were significantly below cost estimates developed by industry. The commenters thought the retrofit factor of 1.2 used by the EPA failed to adequately account for the additional costs incurred when retrofitting an existing emission unit with new controls. They recommended the EPA use the capital costs prepared by industry and apply a retrofit factor of 1.5 or 1.6 with a contingency factor of 30 percent to account for the higher costs for retrofit projects. The commenters also stated that the total annual costs were underestimated because the EPA had underestimated costs for activated carbon, electricity, and waste disposal and used an interest rate that was too low. Industry commenters also stated that currently, some plants recycle iron particles collected by their particulate emission control device, but that the presence of activated carbon would create product quality issues and make recycling no longer possible. The commenters stated the EPA had not accounted for the loss of product and increased waste disposal costs in the cost estimates prepared for the proposal. The commenters provided cost estimates for the Keetac, Minorca, Minntac and UTAC facilities that included estimates of the amount of product they assert would be lost if scrubber solids are not recycled back through the process and the estimated price for the lost product. The commenters also disagreed with the estimated labor costs, arguing that both the number of operator hours and hourly labor rates were too low.

Response: For the final rule, the EPA has updated the capital and annual costs to reflect the costs in 2023 dollars using an interest rate of 8.5 percent and updated unit prices for activated carbon, utilities, and labor. The EPA also assessed the commenters concerns that ACI would prevent plants from recovering iron particles collected with other solids by their particulate emission control device. Based on the information provided by industry, ten indurating furnaces currently collect the solids from their particulate control devices and recycle the solids back to the production process, thereby recovering valuable iron product. Commenters said plants using ACI would not be able to continue to recover iron in this way because carbon would impact the quality of their product. Commenters said EPA should account for costs due to the loss of product and increased cost of waste disposal of the unrecoverable product. Industry provided estimates of the amount of iron that would be lost for the furnaces located at the UTAC, Minorca, and Minntac plants. We used this data to estimate iron losses for the Hibbing plant and multiplied the estimated iron losses for each furnace by the current market price of iron to estimate the costs associated with the loss iron product. The updated cost estimates that we are using for the final rule, including the basis for the 8.5 percent interest rate, are documented in the memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing,* which is available in the docket for this action.

The EPA reviewed the capital cost information submitted by industry during the comment period and found the information submitted consisted of a total capital cost for equipment. However, no breakdown was provided from which we could ascertain what was included in the cost and little information was provided on how the costs were derived. The lack of detail in the cost estimates combined with little supporting documentation made it impossible for the EPA to assess the accuracy of the cost estimates submitted by industry. Industry commenters indicated that the estimated equipment costs for the air pollution control equipment for the Minorca and UTAC facilities they submitted were estimated using cost data from another project at a different facility and scaled using the

'rule of six-tenths.' The 'rule of six-tenths' is a method by which equipment costs are estimated as the cost of a known project multiplied by a capacity factor raised to the power of six-tenths. The 'rule of six-tenths' can provide a reasonable order of magnitude estimate of equipment costs where the capacities of the two systems are reasonably similar. However, the commenters did not identify the facility or provide a detailed description of the project to which they are applying the rule of six-tenths. Commenters also failed to provide a detailed breakdown of the equipment costs used in the 'rule of six-tenths' estimate. Without additional information, the EPA was unable to assess the accuracy of the equipment costs provided by commenters. Therefore, we are not making any changes based on this information.

We disagree with the commenters' recommendations that a retrofit factor of 1.5 or 1.6 should be applied to the capital costs with a 30-percent contingency factor. Retrofit factors account for costs directly related to the demolition, fabrication, and installation of the control system. For the venturi scrubbers we included the 3-percent contingency factor and applied a retrofit factor of 1.2 to the estimate of the total capital investment for new construction. The EPA's *Air Pollution Control Cost Manual* indicates a 3-percent contingency factor is considered appropriate for a mature air pollution control technology and states that retrofit costs are ''generally minimal'' for venturi scrubbers because of their small footprint.[2] While we agree with the commenters that retrofits may, in some cases, be more expensive than new construction, the 1.2 retrofit factor used in the cost estimates provides a reasonable increase to account for the higher cost associated with retrofit projects that involve replacing an existing venturi scrubber with a high-efficiency venturi scrubber, where infrastructure (*e.g.,* water and power supply) already exist. The retrofit factor applied does not have a significant impact on the total annual costs. If a retrofit factor of 1.6 is applied, as recommended by the commenters, the total annual costs would increase by about 2 percent (less than $2 million for replacing the venturi scrubbers on all 11 furnaces with mercury emissions currently exceeding the MACT floor. We did not apply a retrofit factor to the capital costs for the activated carbon injection (ACI) system because the costs were estimated using a methodology developed by Sargent & Lundy for the EPA's Integrated Planning Model (IPM).[3] The IPM methodology is based on costs for retrofitting ACI on utility boilers and therefore already represents the average or typical costs for ACI retrofits.

A contingency factor is reserved for costs that could incur a reasonable but unanticipated increase but are not directly related to the demolition, fabrication, and installation of the system. Retrofit and contingency factors can be difficult to assess as they vary based on site-specific characteristics. Nevertheless, the EPA considers the methodology used to calculate capital and total annual costs to be a reasonable approach to estimating costs for the purposes of this rulemaking. We note that the EPA may not consider costs in determining the MACT floor, and that the cost estimates for the BTF control options identified for Hg emissions were determined to be greater than the level historically found to be cost-effective for controlling Hg emissions.

Comment: Industry commenters noted that the Hg concentrations in taconite ore deposits vary widely both within each mine and between mines, which in turn affects Hg emissions. The commenters said the primary source of Hg emissions from indurating furnaces is from the Hg contained in the greenballs (*i.e.,* unfired taconite iron ore pellets). The commenters provided Hg concentration data for greenballs from each taconite iron ore processing facility and recommended that the EPA revise the proposed Hg limits for new and existing furnaces to address the variability inherent in the Hg concentration of greenballs. They suggested the EPA use the data to develop a raw material variability factor that could be used when calculating the MACT floor limits for Hg. The commenters noted that the EPA had accounted for variability in the Hg concentration of raw materials when calculating the MACT floor limits for other NESHAP.

Response: The EPA reviewed the Hg data submitted by industry and determined the data were not adequate for us to calculate a variability factor for use in deriving the MACT floor limits. This decision was based on several factors. First, the number of measurements submitted for each facility varied considerably—from as few as three measurements for the best performing furnace at Northshore (including two measurements on the same day) to as many as 948 measurements for the UTAC plant. The very limited data provided for Northshore is a concern because Northshore's stack test data showed that their furnace was the best performing (*i.e.,* had the lowest emissions of Hg). The data provided for Northshore are insufficient to evaluate temporal variability in the Hg content of the greenballs at Northshore because the data consist of measurements made during only two greenball sampling episodes: one in January 1997 and the other in November 2001. Second, much of the data submitted could not be validated because the commenters did not provide the laboratory reports for the test results. For example, the UTAC facility provided 948 measurements of the Hg concentration of the greenballs at their plant but submitted none of the laboratory reports needed to corroborate their data. Laboratory reports are needed to determine whether appropriate methods were used for sample collection and analysis, to confirm appropriate quality assurance and quality control measures were taken, and to check that the values submitted are accurate. In total, we were unable to confirm the concentration values for over 87 percent of the measurements submitted because we lacked the laboratory reports. Third, the samples were collected at irregularly spaced intervals, often with large gaps in time during which no samples were collected. These sampling intervals varied from as little as a few days to multiple years. In cases where samples were collected over a period of several consecutive months, the measurements were not collected at consistent intervals. Ideally, the samples would be collected at representative intervals with supporting documentation of the sample collection and analysis, to avoid bias in the dataset. Finally, the data submitted for some facilities included measurements that we determined to be statistical outliers. For example, we identified two statistical outliers in the Tilden dataset, where in one case the Hg content of greenballs increased from 1.4 nanograms per gram (ng/g) on July 6, 2022, to 15.0 ng/g on July 15, 2022, before decreasing to 1.2 ng/g on July 22, 2022. The presence of statistical outliers does not necessarily mean the

[2] EPA's *Control Cost Manual* provides guidance for the development of capital and annual costs for air pollution control devices. The *Control Cost Manual* focuses on point source and stationary area source air pollution controls. A copy of the manual is available at *https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/cost-reports-and-guidance-air-pollution.*

[3] Sargent & Lundy, LLC, *IPM Model—Updates to Cost and Performance for APC Technologies Mercury Control Cost Development Methodology,* January 2017. A copy of this document is available at *https://www.epa.gov/sites/default/files/2018-05/documents/attachment_5-6_hg_control_cost_development_methodology.pdf.*

measurements are incorrect. However, statistical outliers raise concerns over the accuracy and representativeness of the measurements, particularly where no explanation for the anomaly is available.

Comment: Some commenters requested EPA Method 30B be included as an acceptable alternative test method for measuring Hg emissions from indurating furnaces.

Response: In response to the commenters' request, we reviewed EPA Method 30B and determined that this method is appropriate for measuring Hg emissions from indurating furnaces. In the final rule, we have updated the list of approved methods for Hg measurement to include EPA Method 30B, in addition to the proposed methods. The final rule allows owners and operators to use EPA Methods 29 or 30B in 40 CFR part 60, appendix A–8, and the voluntary consensus standard (VCS), ASTM D6784–16, *Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method).*

Comment: Industry commenters expressed concern that the proposed Hg stack testing volumes for performance testing to demonstrate compliance with the proposed Hg standards were too large such that each test run would require too much time to complete. They recommended that smaller test volumes would be appropriate and suggested that the test volume be small enough to allow each test run to be completed within 60 minutes.

Response: In response to the commenters' concerns regarding the stack testing volumes and duration of each test run, the EPA reconsidered the proposed sample volume requirements and revised the performance testing requirements in the final rule to require a minimum sample volume of 1.7 dry standard cubic meters (dscm) (60 dry standard cubic feet (dscf)) for EPA Method 29 and ASTM D6784–16, instead of the 3 dscm sample volume we proposed. The 1.7 dscm sample volume will allow test runs to be completed in approximately 2 hours while still ensuring that the required sample volume is sufficient for analysis and that a non-detect test result indicates compliance with the final Hg limits.

Comment: We received multiple comments recommending continuous emission monitoring systems (CEMS) for Hg be included either as a requirement for all indurating furnaces or as an optional alternative to conducting performance testing and establishing operating limits. The commenters stated that CEMS would ensure continuous compliance with the Hg standard and could help lower compliance costs by making it possible for facilities to vary the ACI rate based on the Hg emissions data collected by CEMS. Some commenters said facilities would be more likely to use CEMS if the CEMS provisions were incorporated into the rule because facilities would not have to apply for approval of an alternative monitoring method.

Response: The EPA agrees with recommendations made by commenters that suggested CEMS be included as an optional alternative to the proposed compliance monitoring and performance testing requirements. We agree that CEMS are an acceptable alternative monitoring method for assuring compliance with the Hg emissions standards. In the final rule, we have included provisions that provide owners and operators the option of using Hg CEMS in lieu of establishing operating limits and performing periodic performance testing. These provisions will provide more options for the methods that facilities can use to demonstrate compliance with the new Hg standards and reduce the burden associated with applying for Administrator approval of an alternative monitoring plan. However, we are not requiring installation of CEMS due to compliance cost considerations, as explained in the memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing,* which is available in the docket for this action.

Comment: Industry commenters were concerned that the proposed approach to setting operating limits for ACI would not allow facilities flexibility to adjust the carbon injection rates when production decreases. These commenters suggested the EPA allow flexibility to adjust the average ACI rate and average carrier flow rate based on taconite pellet production rates during stack testing to provide facilities with the operational flexibility needed at lower production rates.

Response: We agree with the industry commenters that lower ACI and carrier gas flow rates would achieve compliance with the emission limit when production rates are lower than the production rates during the performance test used to establish operating limits. We have included provisions in the final rule that allow a facility to adjust the operating limits based on taconite pellet production. Under the requirements of the final rule, a facility has the option of establishing operating limits for different production rates by conducting performance tests at the maximum, minimum, and median taconite pellet production rates of an indurating furnace to develop a relationship between the carbon injection rate and taconite pellet production rate. An owner or operator would monitor the taconite pellet production rate and adjust the ACI rate in accordance with the relationship between these parameters developed during the performance testing. If the taconite pellet production rate falls below the minimum rate measured during performance testing, the owners and operators must maintain a carbon injection rate that is equal to, or above, the rate determined during the performance testing completed at the minimum taconite production rate.

As an alternative, an owner or operator may adjust the ACI rate based on the direct measurement of Hg emitted to the atmosphere. An owner or operator must install, calibrate, maintain, and operate CEMS to measure Hg emissions from each emission stack associated with the indurating furnace to use this alternative.

Comment: Industry commenters supported the EPA's decision to set the Hg emissions standards at the MACT floor rather than setting a BTF standard. Industry commenters stated that the capital and annual costs required to comply with the MACT floor are too high and setting BTF standards would not be cost-effective. One commenter asserted that any standard beyond the MACT floor must be justified by a ''thorough and robust analysis of the costs and benefits.'' The commenter agreed with the EPA's proposed determination that the cost-effectiveness of the BTF options identified for Hg control were above the level historically found to be reasonable.

Several other commenters recommended the EPA set a BTF Hg standard and recommended the standard be at least 30–40 percent more stringent than the MACT floor. The commenters stated that additional Hg reductions can be achieved and that a more stringent Hg standard is warranted due to the bioaccumulative nature of Hg. The commenter noted that many water bodies located near taconite facilities already have fish consumption advisories, which commenters noted impact the rights of tribes to exercise their traditional life practices. One commenter noted that tribes have a particular interest in Hg emissions due to the Hg-related fish consumption advisories that have been issued by Minnesota since the 1970s and by the Fond du Lac Tribe beginning in 2000. One commenter stated that the 30

percent BTF option would reduce Hg emissions to a level that would help address public health concerns associated with high concentrations of Hg in water, fish tissues, and other subsistence resources. Commenters from several tribes located near taconite facilities stated that the EPA's Tribal trust and treaty responsibilities justified adoption of a BTF option. They added that the EPA should consider its trust responsibility to protect the interests of tribes and the tribes' treaty rights and quoted from two EPA policy documents: *EPA Policy for the Administration of Environmental Programs on Indian Reservations* (issued November 1984) and *Guidance for Discussing Tribal Treaty Rights* (issued February 2016). Both documents support consideration of Tribal rights and protections in Agency decision making. Commenters noted that the areas impacted by taconite iron ore processing plants are in the areas covered by a series of treaties. These commenters disagreed with the EPA's determination that BTF options were not cost-effective.

Response: The EPA agrees with the commenters that said the Hg standard should be set at the MACT floor. In our analysis, the BTF options were above the numbers we have found cost effective for Hg controls in prior CAA section 112 rulemakings.

The EPA recognizes the Federal government's trust responsibility, which derives from the historical relationship between the Federal government and Indian Tribes. The EPA acts consistently with the Federal government trust responsibility by implementing the statutes it administers and consulting with and considering the interests of tribes when taking actions that may affect them. As we noted in the proposal, the EPA consulted with Tribal government officials during the development of this rule. The EPA's Office of Air and Radiation held a meeting with the Fond du Lac Band of Lake Superior Chippewa Reservation and the Leech Lake Band of Ojibwe Reservation on January 12, 2022, to discuss the EPA's CAA section 114 information request, and to ensure that the views of affected tribes were taken into consideration in the rulemaking process in accordance with the *EPA Policy on Consultation and Coordination with Indian Tribes.* A summary of that consultation is provided in the document, *Consultation with the Fond du Lac Band of Lake Superior Chippewa and the Leech Lake Band of Ojibwe regarding Notice of Proposed Rulemaking for the National Emission Standards for Hazardous Air Pollutants for Taconite Iron Ore Processing Amendments on January 12, 2022,* which is available in the docket for this action.

The Agency recognizes the concerns raised by numerous Tribal commenters regarding impacts to treaty fishing and other resource rights. However, for the reasons explained below, the EPA is declining to set BTF standards for Hg, based on the statutory factors that we are required to consider pursuant to CAA section 112(d)(2) when assessing whether to set MACT standards more stringent than the MACT floor level of control. These statutory factors include the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements. As discussed in paragraphs later in this section, the cost-effectiveness values associated with BTF standards for this Taconite Iron Ore Processing rule are well above the cost-effectiveness values that EPA has historically accepted when considering BTF options for regulating mercury emissions. We note that the historic acceptable cost-effectiveness values for mercury (*e.g.,* up to $22,400 per pound [in 2007 dollars] in the 2011 final MATS rule, which equates to about $32,000 per pound in current dollars) are much higher than the cost-effectiveness values we have accepted for all other HAPs (except for maybe a few exceptions such as dioxins and furans) and is based, at least in part, on the fact that mercury is a persistent, bioaccumulative, toxic (PBT) HAP. Nevertheless, we conclude that setting BTF Hg standards in this rule would be inconsistent with the values found to be cost-effective for Hg controls in prior rulemakings. We are declining to set BTF standards in this rule based on cost and other statutory factors.

Section 112(d) of the CAA requires the EPA to set emissions standards for HAP emitted by sources in each source category and subcategory listed under CAA section 112(c). The MACT standards for existing sources must be at least as stringent as the average emissions limitation achieved by the best performing 12 percent of existing sources (for which the Administrator has emissions information) or the best performing five sources for source categories with less than 30 sources (CAA sections 112(d)(3)(A) and (B)). This level of minimum stringency is called the MACT floor. For new sources, MACT standards must be at least as stringent as the control level achieved in practice by the best controlled similar source (CAA section 112(d)(3)). The EPA may not consider costs or other impacts in determining the MACT floor.

Section 112(d)(2) of the CAA also requires the EPA to examine emission standards more stringent than the MACT floor, which the EPA refers to as BTF control options. Unlike standards set at the MACT floor level of control, when assessing whether to require emission standards more stringent than the MACT floor, the EPA must consider the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements. The EPA's BTF analysis evaluated these factors in determining whether to establish Hg standards more stringent than the MACT floor. In developing this final rule, we evaluated Hg emission limits more stringent than the MACT floor after adjusting estimates of Hg emissions, Hg emission reductions, and control costs as discussed above, including those BTF limits suggested by commenters, to assess whether a BTF option was technically achievable and cost-effective. We estimate that the total capital costs and total annual costs would range from a low of $137 million and $92 million, respectively, for a limit that is 10 percent more stringent than the floor to a high of $148 million and $102 million, respectively, for a limit that is 40 percent more stringent than the floor. The incremental cost effectiveness for the BTF options examined varied from a low of $46,266 per pound of Hg reduced for 30 percent more stringent than the floor to a high of $91,140 per pound of Hg reduced for 40 percent more stringent than the floor. These values are well above the $/pound of Hg reduced that we have historically found to be cost-effective when considering BTF options for regulating Hg emissions. Where EPA has taken costs into account, the Agency has finalized standards for mercury with cost effectiveness estimates of up to $32,000/lb Hg reduced (adjusted to 2024 dollars). See Mercury Cell Chlor-Alkali Plants Residual Risk and Technology Review (87 FR 27002, May 6, 2022); 2011 Mercury and Air Toxics (MATS) final rule. To date, these are the highest cost-effectiveness values that we have accepted in the air toxics program for any HAP (except for maybe a few exceptions such as dioxins and furans), largely because of the toxicity and nature of Hg. While we conclude that mercury standards more stringent than the MACT floor are not cost-effective, we note that as a result of the revisions to the rule being finalized in this rulemaking, we will receive compliance test information that will allow us to evaluate our conclusions and potentially inform appropriate future

regulatory activities including the next statutorily required technology review. Mercury is one of the high concern HAPs because it is environmentally persistent, it bioaccumulates in humans and food chains—including in fish, which is a concern for subsistence needs, uses and cultural practices as noted in multiple comments from Tribes—and is a neurotoxin that is especially of concern for developing fetuses and young children. For these reasons, mercury is one of the few HAPs for which we use the expression of $ per pound and consider higher cost-effectiveness values. We also estimated the secondary impacts of the BTF options would range between 155,000 megawatt-hours per year (MWh/yr) and 160,000 MWh/yr of electricity (with associated secondary air emissions), generate between 4.7 million and 7.4 million gallons of wastewater per year, and produce between 110,000 tons and 112,000 tons of solid waste of per year. Based on our assessment of Hg emission standards 10 percent, 20 percent, 30 percent, and 40 percent more stringent than the MACT floor, including consideration of cost and other statutory factors of setting BTF Hg standards for indurating furnaces in the source category as specified in CAA section 112(d)(2), in the final rule, we are declining to adopt BTF emission standards for Hg and are finalizing Hg standards at the MACT floor as discussed in section III.A.3 of this preamble. For more information on our analysis of the BTF control options for Hg, please see the memorandum, *Final Maximum Achievable Control Technology (MACT) Analysis for Mercury Standards for Taconite Iron Ore Indurating Furnaces,* which is available in the docket for this action.

Comment: Several commenters, including the National Park Service, several local tribes, and environmental organizations said Hg standards for the taconite industry were important because of the benefits lower Hg emissions will have on public health and the environment. One commenter cited several studies, such as the Dragonfly Mercury Project, that document elevated levels of Hg and higher risks of Hg exposure to humans and wildlife in the Great Lakes Region. This commenter stated that the upper Great Lakes Region is particularly sensitive to Hg pollution due to the abundance of wetlands and peatlands, low-pH lakes, high dissolved organic matter, low biological productivity, and other factors that provide conditions suitable for the conversion of Hg to the bioavailable form methylmercury. The commenter also stated the impacts of Hg on wildlife include reduced foraging efficiency, lower reproductive success, impaired endocrine modulation, and damage to kidney and other tissues. The commenters expressed concern over the number of fish with Hg levels exceeding the human and wildlife health thresholds. The commenter cited data from a 1998–2016 study that measured Hg concentrations in fish from the upper Great Lakes at 0.12 ppm wet weight, with 24 percent of the fish sampled exceeding the EPA human health criterion of 0.3 ppm wet weight, 27 percent of the fish exceeding fish-eating wildlife health threshold of 0.2 ppm whole-body, and 17 percent exceeding the fish toxicity benchmark of 0.3 ppm whole-body. This commenter cited studies linking Hg deposition with bioaccumulation, including a study of Hg concentration in moose teeth from Isle Royale National Park, Michigan from 1952 to 2002. The commenter noted that Hg decreased by about two-thirds during the early 1980s but remained constant for the following 2 decades. The commenter cited an additional six studies that analyzed the concentrations and trends of Hg in bald eagle nestlings in the upper Midwest from 2006–2015 and long-term trends at two Lake Superior sites between 1989–2015. These studies show concentrations of Hg in nestling breast feathers were highest at the Saint Croix National Scenic Riverway (6.66 μg/g wet weight) and that Hg concentrations have increased at two other study area sites.

The commenters said the new Hg standards will help reduce Hg deposition in the Great Lakes Region and improve public health. The commenters asserted that taconite iron ore processing plants in Minnesota and Michigan have a significant impact on the natural resources of the upper Great Lakes Region and the elevated Hg levels in fish and bird populations. Several commenters mentioned the statewide fish consumption advisories for Hg in Minnesota, Michigan, and Wisconsin and noted several water bodies in these states are listed as impaired for aquatic consumption due to Hg. The commenters asserted that the new Hg standards will reduce the impact of Hg on public health and the environment, provide additional protection to recreational and subsistence fish consumers in national parks and surrounding communities, and protect natural resources that are of cultural significance to many local communities.

Response: The EPA acknowledges the independent research conducted by the National Park Service and others on the impacts of Hg on the communities and wildlife of the upper Great Lakes Region. We share the commenters' concern about the elevated Hg levels in fish and other wildlife in Minnesota, Wisconsin, and Michigan, and the critical impact these Hg levels have on tribes and low-income populations that rely on the fish and wildlife from the Great Lakes region. By controlling Hg emissions, the Hg MACT standards EPA is finalizing in this action for taconite iron ore processing plants will achieve an estimated reduction of 247 pounds per year of mercury emissions from the Taconite facilities, which we expect will also achieve an unquantified reduction of Hg deposition in the Great Lakes Region and therefore improve public health of local communities, including local tribes and low-income populations.

3. What are the final MACT standards for Hg and how will compliance be demonstrated?

We are finalizing MACT standards for Hg for new and existing indurating furnaces that reflect the MACT floor level of control, based on the 99-percent UPL, of 1.4×10^{-5} lb/LT for existing sources and 2.6×10^{-6} lb/LT for new sources. We are also finalizing the emissions averaging compliance alternative that allows taconite iron ore processing facilities with more than one existing indurating furnace to comply with a Hg emissions limit of 1.3×10^{-5} lb/LT by averaging emissions on a production-weighted basis for two or more existing indurating furnaces located at the same facility.

Owners and operators may demonstrate compliance with the new Hg standards in one of two ways. Under the first option, an owner or operator may demonstrate compliance by completing performance testing and establishing operating limits for each control device used to comply with the Hg standard. The final rule clarifies that performance testing must be performed when the production rate is equal to or greater than 90 percent of the capacity of the indurating furnace. If the performance testing cannot be performed when the production rate is equal to or greater than 90 percent of the production rate capacity of the furnace, the owner or operator may complete testing at a lower production rate if they receive approval from the delegated authority. An owner or operator selecting this option must install and operate continuous parameter monitoring systems (CPMS) to monitor the parameters specified in 40 CFR 63.9631(g). An owner or operator must take corrective action when an established operating limit is exceeded.

The initial performance testing must be completed within 180 calendar days of the compliance date specified in 40 CFR 63.9583(f) for existing sources or within 180 calendar days of startup for new sources, using EPA Methods 29 or 30B in 40 CFR part 60, appendix A–8 or the VCS ASTM D6784–16, *Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method).* The performance tests must be repeated at least twice per 5-year permit term.

The second option by which an owner or operator may demonstrate compliance is through the installation and operation of CEMS for Hg. The CEMS must be installed, calibrated, maintained, and operated in accordance with the procedures specified in 40 CFR 63.9631(j). An owner or operator selecting this approach is not required to establish operating limits, install and operate CPMS, or complete the initial and periodic performance testing for Hg emissions.

As discussed in section III.A.2 of this preamble, the final rule includes an option for adjusting the carbon injection rate based on the taconite pellet production level. The facility has the option of establishing operating limits for different production rates by conducting performance tests at the maximum, minimum and median taconite pellet production rates to develop a relationship between carbon injection rate and taconite pellet production rate or by adjusting the ACI rate based on Hg emissions data collected by CEMS. Facilities that elect to adjust the carbon injection rate based on taconite production levels will have lower compliance costs due to lower annual consumption of activated carbon.

Each owner or operator must prepare a preventive maintenance plan and keep records of calibration and accuracy checks of the CPMS or CEMS to document proper operation and maintenance of all monitoring systems used to demonstrate compliance with the applicable Hg standard.

B. Revised Emission Standards for HCl and HF

1. What did we propose for the Taconite Iron Ore Processing source category?

As described in the May 15, 2023, proposal (88 FR 30917), we proposed to revise the numerical emission limits for HCl and HF, pursuant to CAA section 112(d)(6). CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years; we refer to such action under CAA section 112(d)(6) as a ''technology review.'' The EPA previously completed a technology review for the Taconite Iron Ore Processing source category in 2020 (85 FR 45476; July 28, 2020). In the May 15, 2023, proposal, we proposed to revise the HCl and HF standards based on new information we obtained in response to the 2022 information collection concerning emissions of these pollutants from the source category. For existing indurating furnaces, we proposed emissions standards of 4.4×10^{-2} lb/LT for HCl and 1.2×10^{-2} lb/LT for HF. For new indurating furnaces, we proposed emission standards of 4.4×10^{-4} lb/LT for HCl and 3.3×10^{-4} lb/LT for HF. We proposed to require that owners or operators demonstrate compliance through initial and periodic performance testing (completed at least twice per 5-year permit term), establishing operating limits for each control device used to comply with the HCl and HF standards, and installing and operating continuous parameter monitoring systems (CPMS) to ensure continuous compliance with the standards.

2. What comments did we receive on the proposed revised HCl and HF emission standards, and what are our responses?

Comment: We received comments and data from industry identifying errors in the emissions data for the Tilden and Hibbing indurating furnaces submitted to the EPA in response to the CAA section 114 information request sent to the taconite facilities in 2022. For the Tilden stack test report, industry confirmed the units of measure were incorrectly listed in the stack test report submitted by industry as ''pounds per ton'' instead of ''pounds per long ton'' of taconite pellets produced. Commenters confirmed the units of measure should be ''pounds per long ton.'' For Hibbing, the commenters identified one transcription error in the HCl emissions data for one of the four emission stacks.

Response: In response to these comments, the EPA reviewed all stack test runs for the seven furnaces that completed HCl and HF stack testing pursuant to the 2022 CAA section 114 information request. We confirmed there was a transcription error in HCl emissions for the first run of the stack testing completed on the Hibbing furnace. Since the emissions data for Hibbing were included in the dataset used to calculate the proposed HCl emission limit, we recalculated the emission limit for HCl using the revised data. As a result of the changes to the Hibbing emissions data, the numerical emission standard for HCl for existing sources was revised from the proposed 4.4×10^{-2} lb/LT to the 4.6×10^{-2} lb/LT limit we are finalizing in this action. The revisions to the emissions data do not impact the numerical limit for HCl for new sources or the numerical limits for HF for new and existing sources. Therefore, the proposed HCl standard for new sources of 4.4×10^{-4} lb/LT and the HF standards for new and existing sources of 3.3×10^{-4} lb/LT and 1.2×10^{-2} lb/LT, respectively, are finalized without change.

The EPA revised the units of measure for the Tilden HCl and HF emission data based on the comments we received from industry. As we explained in the proposal, the HCl and HF emissions data for the Tilden furnace are not used to calculate the emission limits for HCl and HF because Tilden's furnaces use dry electrostatic precipitators (ESP). In the proposal, we stated that we expect Tilden's two indurating furnaces would be able to meet the HF limit for existing furnaces without adding any air pollution control devices but that we expect Tilden would be required to add air pollution control devices to meet the proposed HCl emission standard. Although the revised emission rates for Tilden are slightly lower than the emissions rates used for the proposal, we expect that Tilden's furnaces would still need to add air pollution controls to meet the HCl emission standard we are finalizing for existing furnaces. As explained in the previous paragraph, the EPA is finalizing the HCl emission standard of 4.6×10^{-2} lb/LT for existing sources. To comply with the HCl emission standard, Tilden must reduce HCl emissions by 76 percent (compared to 79 percent HCl reduction we estimated at proposal) and the HCl emissions reduction for the final rule is 683 tpy (compared to a 713 tpy reduction we estimated at proposal). Our revised total capital cost estimate for HCl controls (dry sorbent injection) is $1.1 million and our revised annual cost estimate is $1.4 million. The revised cost effectiveness is $2,040 per ton of HCl removed, which is a level of cost effectiveness that is acceptable for HCl and would also likely be acceptable for any other HAP. The revised emissions data, numerical limits, and cost estimates prepared for the final rule are documented in the memorandum, *Final Revised Technology Review of Acid Gas Controls for Indurating*

Furnaces in the Taconite Iron Ore Processing Source Category, which is available in the docket for this action.

Comment: Multiple commenters were supportive of replacing PM as a surrogate for HCl and HF emissions and supported the proposed numerical emission limits for HCl and HF. One commenter said the PM limit was not a valid surrogate for emissions of HCl and HF and argued the EPA should set HCl and HF limits under the provisions of CAA section 112(d)(2) and (3). However, other commenters from industry disagreed with our proposal and said the existing standards based on PM as a surrogate for acid gases should not be changed. These commenters asserted that the EPA lacked the authority to revise the existing HCl and HF standards because the EPA had not shown that technological developments have occurred that would lower emissions of acid gases nor shown that revisions are necessary, as required by CAA section 112(d)(6). The commenters stated that new emissions data does not qualify as a development under CAA section 112(d)(6) and that the language in CAA section 112(d)(6) focuses on actual control measures and requires the EPA to update an existing emissions standard only if improvements in control measures occur and the improvements in control measures warrant a revision. The commenters added that PM is still recognized as a proper surrogate for HAP emissions and the revised standards are unnecessary because they impose a significant financial burden on taconite iron ore processing plants without reducing risks to the public health and the environment.

Response: The EPA agrees that revising the emission limits for HCl and HF is appropriate for the reasons explained in this discussion, below, and in the proposal preamble (88 FR 30926). We disagree that the EPA lacks authority to revise the existing standards for HCl and HF. When the NESHAP for the Taconite Iron Ore Processing source category was first developed, PM emission limits were used as a surrogate for HCl and HF. The decision to use the PM standards as a surrogate for HCl and HF emissions was based on an analysis of the HCl, HF, and PM emissions data that the EPA possessed at the time of promulgation of the initial NESHAP for the Taconite Iron Ore Processing source category in 2003 (68 FR 61868; October 30, 2003). That data indicated there was a correlation between acid gas and PM emissions. We note, however, that the use of PM as a surrogate for HCl and HF and the corresponding PM emission limit were based on a limited dataset because only three furnaces conducted PM emissions tests concurrently with the HCl and HF tests. As part of the 2022 CAA section 114 information request, the EPA sought emissions data from Taconite Iron Ore Processing facilities, including stack testing for PM, HCl, and HF emissions from seven indurating furnaces located at six taconite facilities. The data received in response to the 2022 CAA section 114 information request are presented in the memorandum, *Final Emissions Data Collected in 2022 for Indurating Furnaces Located at Taconite Iron Ore Processing Plants,* which is available in the docket for this action. The 2022 dataset is not only more robust than the limited dataset available in 2003 but also more representative of current conditions since some of the control devices used on the furnaces at the time of the 2003 rulemaking have changed since that time. For example, the Keetac plant has since replaced the multicyclones on their indurating furnace with venturi scrubbers and the Tilden plant replaced a wet ESP on one stack with a dry ESP. Based on this new data, we determined it was more appropriate to directly regulate the HAP of concern than to use a surrogate. Our analysis of the 2022 data and our review of available air pollution controls for acid gases indicates that the controls we expect will be necessary to meet the numerical standards for HCl and HF are available and cost-effective. As we explained in the proposal (88 FR 30926), the new data received in response to the 2022 CAA section 114 information request showed that indurating furnaces using wet scrubbers achieve better control of HCl and HF than furnaces using dry ESP.

We disagree with commenter that we lack the authority to revise standards pursuant to CAA section 112(d)(6) absent a showing that the revisions would reduce risk. CAA section 112(d)(6) requires the EPA to review and revise as necessary emission standards taking into account developments in practices, processes, and control technologies. This provision does not require the EPA to consider risk. We agree that the EPA has the discretion to consider cost when considering the appropriate level of control under CAA section 112(d)(6). The EPA identified dry sorbent injection (DSI) and wet scrubbers as a feasible control options and estimated the associated costs. We concluded that DSI is the lowest cost option for the indurating furnaces located at the Tilden plant. Based on this analysis, the EPA concluded the costs to comply with the numerical limits for HCl were justified and cost-effective and do not impose a significant financial burden on industry. The cost effectiveness was estimated to be $2,040 per ton of HCl removed, which is within the range the EPA has previously considered to be a cost-effective level of control for many HAP. Based on the 2022 emissions data, add on air pollution controls are not required to meet the HF emission limit. The standards we are finalizing in this action ensure HCl and HF emissions from all indurating furnaces in the source category are controlled to the same extent as the best performing indurating furnaces in the source category.

Comment: Industry commenters stated there is no basis for changing the way HCl and HF emissions are regulated, that the EPA did not explain why PM cannot be used as a surrogate for HCl and HF emissions, and that if revised standards were needed, they should be based on the subcategories established in the Taconite Iron Ore Processing NESHAP in 2003. The commenters stated that the EPA should make determinations on whether new standards are necessary for each subcategory and then should base any new standards for each subcategory on emission data for the furnaces within that subcategory. The commenters acknowledged that CAA section 112(d)(6) authorizes the EPA to review and revise as necessary the emission standards every 8 years, but they said the statute does not permit the EPA to develop new standards ignoring the existing subcategories. The commenters argued the Tilden facility processes a different type of taconite ore (*i.e.,* hematite instead of magnetite) than the other facilities and therefore the furnaces at this facility should remain in a separate subcategory from the furnaces at the other facilities (as was the case when the EPA established the PM standards in the 2003 NESHAP). The commenters noted that a subcategory was established for grate kilns processing hematite ore because of differences in the ore and furnace, including different air flow direction and rates, the perpetual motion of the pellets inside the kiln, fineness of the hematite ore, tendency for the hematite pellets to break, and production of fluxed pellets that use limestone/dolomite containing chloride. For furnaces that process magnetite, the commenters argued that limits for HCl and HF are not needed and would result in unnecessary compliance costs

without health and environmental benefits.

Response: We disagree with the industry commenters' assertion that the EPA should extend the subcategorization for PM standards used in the 2003 rulemaking and set HCl and HF limits only for grate kilns processing hematite ore. When the NESHAP for the Taconite Iron Ore Processing source category was initially developed, indurating furnaces were identified as significant sources of HCl and HF emissions. The NESHAP promulgated in 2003 established limits, as required under CAA section 112(d), for all indurating furnaces. The decision to use the PM standards as a surrogate for HCl and HF emissions was based on very limited HCl, HF, and PM emissions data available and evaluated for the 2003 rulemaking. As we explained in the response to the previous comment, in this action, we have determined it is more appropriate to directly regulate the HAP of concern (*i.e.,* HCl and HF) than to use a surrogate, using the more robust 2022 dataset now available to us. The data collected for this rulemaking are presented in the memorandum, *Final Emissions Data Collected in 2022 for Indurating Furnaces Located at Taconite Iron Ore Processing Plants,* which is available in the docket for this action.

We disagree with commenters' assertion that emission limits for acid gases should be established using the existing subcategories for PM and that HCl and HF standards are not necessary for furnaces that process magnetite ore. The EPA found in the 2003 NESHAP final rule that HCl and HF are emitted by all indurating furnaces and established standards for all types of indurating furnaces in the Taconite Iron Ore Processing source category, including those indurating furnaces that process magnetite ore. Indeed, the emissions data collected in response to the 2022 CAA section 114 information request demonstrate that indurating furnaces processing magnetite ore emit measurable levels of HCl and HF even after control by wet scrubbers. HCl and HF are formed in indurating furnaces due to the presence of chlorides and fluorides in the raw materials used to form the greenballs (*i.e.,* unfired taconite pellets) that are fed into the indurating furnaces. While some of the chlorides and fluorides in the raw materials come from the ore, pellet additives, such as dolomite and limestone, are also a source of HCl and HF emissions. These additives are routinely used by all taconite plants, including those that process magnetite ore. Although the commenters suggested plants processing hematite ore using grate-kilns should be considered a separate subcategory when considering acid gas emissions, the commenters provided no data demonstrating a significant difference in the chloride and fluoride content of the two types of ores. Nor did they provide any explanation or data to support their assertion that differences in the design of the indurating furnace impact HCl and HF emissions. The data pertaining to indurating furnaces processing magnetite ore that was collected in response to the 2022 CAA section 114 information request does not show a significant difference in acid gas emissions between straight-grate and grate kiln indurating furnaces.

Pursuant to CAA section 112(d)(1), the Administrator ''may distinguish among classes, types, and sizes of sources within a category or subcategory in establishing'' standards. However, as we have discussed in previous Agency actions, the CAA does not mandate that the EPA create subcategories. See, *e.g., National Emission Standards for Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units* (77 FR 9304, 9378; February 16, 2012) (''2012 Mercury and Air Toxics Final Rule''). In addition, the Agency may create subcategories for the purpose of regulating specific HAP, while declining to create subcategories more broadly. In the 2012 Mercury and Air Toxics Final Rule, we explained the Agency's position that any basis for subcategorization (*i.e.,* class, type, or size) typically must be related to an effect on HAP emissions that is due to the difference in class, type, or size of the sources. We further explained that ''[e]ven if we determine that emissions characteristics are different for units that differ in class, type, or size, the Agency may still decline to subcategorize if there are compelling policy justifications that suggest subcategorization is not appropriate'' (77 FR 9378). In the 2012 Mercury and Air Toxics Final Rule, we determined it was appropriate to subcategorize coal-fired boilers for purposes of regulating Hg emissions based on differences in Hg emissions between two types of coal-fired boiler subcategories. We also determined that for all other HAP, the data did not show any difference in HAP emission levels, and we declined to set separate emission standards for the two types of coal-fired boilers for other HAP.

In this final rule, we are retaining the separate PM emission limits established in the 2003 final rule for indurating furnaces processing magnetite and hematite. Based on the data available, we continue to believe it is appropriate to retain these separate PM emission standards because hematite is a finer grained ore than magnetite, and processing of hematite in an indurating furnace results in higher PM emissions than processing magnetite. However, we are declining to subcategorize taconite indurating furnaces for purposes of regulating Hg or acid gas emissions. As explained previously, pursuant to CAA section 112(d)(1), the EPA has the discretion to subcategorize sources for the purpose of setting emission standards under CAA section 112, but is not required to do so. As we also explained, where the EPA elects to subcategorize sources, we typically do so for the purpose of setting standards for specific HAP where the basis for the subcategorization is related to an effect on HAP emissions that is due to a difference in class, type, or size of the sources. The differences in emissions of HCl and HF among taconite indurating furnaces are largely the result of differing controls utilized by sources rather than a result of the class, type, or size of the indurating furnaces themselves. Therefore, we conclude that the differences in HCl and HF emissions are not due to differences in the class, type, of size of taconite indurating furnaces. As a result, we do not believe it is appropriate to subcategorize taconite indurating furnaces for the purpose of regulating Hg, HCl, or HF emissions and are declining to do so in this final rule.

Based on the data available, the EPA proposed to set HCl and HF emission standards that apply to all indurating furnaces. In this action, we are finalizing emission standards for HCl and HF as discussed in section III.B.1 of this preamble. While the HCl emission standard for existing furnaces differs from what we proposed for the reasons explained in section III.B.2 of this preamble, we continue to believe it is appropriate to set numerical emission standards for HCl and HF based on the 2022 ICR data rather than to continue to rely on PM standards as a surrogate for these pollutants. While we expect that most indurating furnaces will be able to meet the revised HCl and HF limits using existing air pollution controls, the new performance testing and parametric monitoring requirements are necessary to ensure continuous compliance with the HCl and HF emission standards. The

PM testing and monitoring requirements in the current NESHAP designed to ensure compliance with the PM emission standards, which will remain in place as surrogates for non-Hg metal HAP, are not sufficient to demonstrate compliance with the HCl and HF emission standards. Each owner and operator must complete performance testing, establish operating limits for each control device used to control HCl and HF, and monitor the appropriate parameters to demonstrate the control device is operating in a manner that ensures compliance with the HCl and HF emission standards. Performance testing must be completed at least twice per 5-year permit term and within 180 days of startup of new furnaces.

Comment: Industry commenters asserted the data used to develop the numerical standards for HCl and HF was too limited to reflect the operational and seasonal variability in the HCl and HF emissions. They stated that several factors influence the HCl and HF emissions and that the emissions data received in response to the 2022 CAA section 114 information request covers too short of a time period to be representative of the acid gas emissions from indurating furnaces. The commenters noted that HCl and HF emissions are driven by the chloride or fluoride content in the iron ore and that the limited dataset does not account for the full range of variability in the chlorine and fluorine content of raw materials. They stated that the raw materials vary throughout a taconite mine, producing raw materials with different compositions and characteristics that are not reflected in the 2022 CAA section 114 information request data. The commenters recommended the HCl and HF limits be based on a more representative dataset collected over a longer period of time that accounts for raw material variation as well as seasonal and operational variation. The commenters stated that because the proposed limits are based on a limited dataset that does not fully account for operational variability, the proposed HCl and HF emission limits should not be finalized and they recommended that the PM standards in the current NESHAP continue to be used as a surrogate for acid gas emissions.

Response: The method used to calculate the proposed numeric emission limits for HCl and HF for new and existing taconite indurating furnaces has been used for several years to set numerical limits for other source categories and is an appropriate methodology that accounts for variability in the emissions between different furnaces and different plants and accounts for some variability in the chloride and fluoride content of the ore and pellet additives used at different facilities because it includes data from two different types of indurating furnaces (straight grate furnaces and grate kiln furnaces) at five different taconite facilities. We used the emissions data from the six indurating furnaces currently using wet scrubbers to calculate a UPL. The UPL approach encompasses all the data point-to-data point variability within the sample set (*i.e.,* all of the emissions data from the six indurating furnaces equipped with wet venturi scrubbers), which consisted of 21 individual data points. The UPL was calculated as the mean of the 21 data points plus a factor that accounts for the variability within the dataset. The UPL represents the value which one can expect the mean of a specified number of future observations (*e.g.,* 3-run average) to fall below at a specified level of confidence based upon the results of an independent sample from the same population. We used a 99-percent level of confidence to calculate the UPL, which means that a facility that uses the same or similar type of air pollution control device(s) has one chance in 100 of exceeding the emission limit. A prediction interval for a single future observation (or an average of several test observations) is an interval that will, with a specified degree of confidence, contain the next (or the average of some other pre-specified number of) randomly selected observation(s) from a population. The UPL estimates what the upper bound of future values will be based upon present or past background samples taken. While larger datasets are always preferable, numerical emission limits are often based on data from a single stack test event. For additional information on the methodology used to develop the numerical emission standards for HCl and HF for the final rule, please see the memorandum, *Final Revised Technology Review of Acid Gas Controls for Indurating Furnaces in the Taconite Iron Ore Processing Source Category.* A copy of this document is available in the docket for this action.

3. What are the revised standards for HCl and HF and how will compliance be demonstrated?

We are finalizing numerical emission limits for HCl and HF, pursuant to CAA section 112(d)(6). We are finalizing as proposed the numerical emission limit for HCl for new indurating furnaces. We are finalizing a numerical emission limit for HCl for existing indurating furnaces which differs from the limit proposed because the final limit reflects a revision to the emissions data for the Hibbing facility, as discussed in section III.B.2 of this preamble. We are finalizing as proposed the numerical emission limits for HF for new and existing indurating furnaces. For existing indurating furnaces, we are finalizing an HCl emission limit of 4.6×10^{-2} lb/LT and are finalizing an HF emission limit of 1.2×10^{-2} lb/LT. For new indurating furnaces, we are finalizing an HCl emission limit of 4.4×10^{-4} lb/LT and are finalizing an HF emission limit of 3.3×10^{-4} lb/LT. Further discussion of the HCl and HF emission standards and the methodology used to develop the emission standards, as well as a discussion of costs, may be found in the memorandum, *Final Revised Technology Review of Acid Gas Controls for Indurating Furnaces in the Taconite Iron Ore Processing Source Category,* which is available in the docket for this action.

We are also finalizing as proposed the requirement to complete performance testing for HCl and HF using EPA Method 26A and to establish operating limits for each control device used to comply with the HCl and HF standards, in accordance with the amended provisions of 40 CFR 63.9622. The final rule clarifies that the owner or operator must perform performance testing when the pellet production rate is equal to or greater than 90 percent of the capacity of the indurating furnace. If the performance testing cannot be performed at or above 90 percent of capacity of the indurating furnace, the owner or operator may complete testing at a lower production rate if they receive approval from the delegated authority. The owner or operator must install and operate CPMS in accordance with the requirements of 40 CFR 63.9633 and must prepare a preventive maintenance plan and keep records of calibration and accuracy checks of the CPMS to document proper operation and maintenance of each monitoring system. An owner or operator must take corrective action when an established operating limit is exceeded. The owner or operator must complete the initial performance tests within 180 calendar days of the compliance date for existing furnaces, or within 180 calendar days of startup for new furnaces. The performance tests must be repeated at least twice per 5-year permit term.

C. What other amendments are we finalizing?

1. Requirement To Complete Performance Testing Within 7 Calendar Days

The EPA proposed amendments to the performance testing provisions that would require the owner or operator to complete a performance test on a source within 7 calendar days of initiating that performance test. This provision was included for the existing performance testing for PM, as well as for the proposed new performance testing for Hg, HCl, and HF. We received one comment that resulted in changes to the proposed requirements. The comment and our response are summarized below.

Comments: Industry commenters opposed the proposed requirement that all performance testing be completed within 7 calendar days because some emission sources have multiple stacks and testing of multiple stacks could require more than 7 days to complete. They also stated that unanticipated shutdowns due to process upsets may prevent tests from being completed within 7 days. The commenters recommended that the EPA allow facilities to notify the Administrator when a longer time frame is needed but asserted that facilities should not be required to obtain approval if more than 7 calendar days are needed to complete performance testing.

Response: We consider the 7 calendar day period to complete all performance testing to be reasonable based on our previous experience with performance testing at industrial facilities. We believe it is unlikely that a facility would be unable to complete the required performance testing within a 7 calendar day timeframe. However, we acknowledge the commenters' concerns that unanticipated shutdowns can occur due to equipment failures or process upsets. To address such circumstances, we included the phrase ''to the extent practicable'' in the final rule. We have finalized the proposed requirement that performance tests be completed within 7 calendar days of the date on which the first test run was started. However, we agree with the commenters' suggestion that owners and operators be required to notify the Administrator when a performance test cannot be completed within 7 calendar days. In the final rule, we revised the proposed language in 40 CFR 63.9620(b)(2), 63.9620(k)(2), and 63.9630(b) to require facilities that will not be able to complete performance tests within 7 calendar days to notify the Administrator within 24 hours of making the determination that they will not be able to do so.

2. Amendments to the Electronic Reporting Requirements

We are also finalizing as proposed changes to the electronic reporting requirements found in 40 CFR 63.9641(c) and 40 CFR 63.9641(f)(3) to reflect new procedures for reporting CBI, including adding an email address that an owner or operator may use to electronically submit compliance reports containing CBI to the OAQPS CBI Office. We received no comments on these proposed amendments.

D. What are the effective and compliance dates for the mercury, HCl, and HF emission standards?

The revisions to the MACT standards promulgated in this action are effective on March 6, 2024. For all affected sources that commence construction or reconstruction before May 15, 2023, we are finalizing, as proposed, that an owner or operator must comply with the new Hg emission standard and revised HCl and HF standards no later than 3 years after the effective date of the final rule. For all affected sources that commenced construction or reconstruction on or after May 15, 2023, we are finalizing, as proposed, that owners and operators comply with provisions by the effective date of the final rule or upon startup, whichever is later. For existing sources, CAA section 112(i)(3) requires compliance ''as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard'' subject to certain exemptions further detailed in the statute.[4] In determining what compliance period is as ''expeditious as practicable,'' we examine the amount of time needed to plan and construct projects and change operating procedures. Since some existing sources may need to install new add-on controls to comply with the Hg, HCl, and/or HF standards, we determined that a period of 3 years is appropriate to allow owners and operators time to plan, design, construct, begin operating the new add-on controls, and conduct performance testing.

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

The Taconite Iron Ore Processing NESHAP applies to the owner or operator of a taconite iron ore processing plant that is (or is part of) a major source of HAP emissions. A taconite iron ore processing plant is any facility engaged in separating and concentrating iron ore from taconite ore to produce taconite pellets. Taconite iron ore processing includes the following processes: liberation of the iron ore by wet or dry crushing and grinding in gyratory crushers, cone crushers, rod mills, and ball mills; concentration of the iron ore by magnetic separation or flotation; pelletizing by wet tumbling with a balling drum or balling disc; induration using a straight grate or grate kiln indurating furnace; and finished pellet handling. A major source of HAP is a plant site that emits, or has the potential to emit, any single HAP at a rate of 9.07 megagrams (10 tons) or more, or any combination of HAP at a rate of 22.68 megagrams (25 tons) or more per year from all emission sources at the plant site. There are currently seven major sources subject to the Taconite Iron Ore Processing NESHAP that are operating in the United States with six located in Minnesota and one located in Michigan. One additional major source located in Michigan, Empire Mining, is subject to the Taconite Iron Ore Processing NESHAP and has a permit to operate but has been indefinitely idled since 2016.

B. What are the air quality impacts?

To meet the Hg emission limits we anticipate that five of the taconite iron ore processing plants would likely need to install additional controls on their indurating furnaces. To meet the HCl and HF emission limits, we anticipate that one additional taconite iron ore processing plant would likely need to install additional controls on their indurating furnaces. We estimate that the installation of such controls will reduce Hg emissions by 247 pounds per year (0.12 tpy) and HCl and HF emissions by 683 tpy and 36 tpy, respectively.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*e.g.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment. As explained in the memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing,* which is available in the docket for this action, we find that the secondary air emissions impacts of this

[4] *Association of Battery Recyclers* v. *EPA,* 716 F.3d 667, 672 (D.C. Cir. 2013) (''Section 112(i)(3)'s 3-year maximum compliance period applies generally to any emission standard . . . promulgated under [section 112]'' (brackets in original)).

action are minimal. The memorandum includes a detailed discussion of our analysis of emissions reductions and potential secondary impacts.

This rule is expected to limit emissions of directly emitted $PM_{2.5}$, which will in turn reduce ambient concentrations of $PM_{2.5}$ and in turn benefit public health. Though EPA neither quantified nor monetized these benefits, we anticipate reducing $PM_{2.5}$ concentrations will reduce the incidence or premature death, non-fatal heart attacks, cases of aggravated asthma, lost days of work and school and other adverse effects (U.S. EPA, 2022).[5] EPA has generated benefit per ton estimates for directly emitted $PM_{2.5}$ reductions from the taconite sector valued at $60,600/ton (2016$).[6] In addition, there are estimates for secondarily-formed $PM_{2.5}$ from reductions in SO_2 emissions valued at $32,800/ton (2016$). However, EPA did not conduct a comprehensive benefit-cost analysis for this rulemaking. This rule is also expected to reduce emissions of Hg. Methylmercury (MeHg), which is formed by microbial action in the top layers of sediment and soils, after mercury has precipitated from the air and deposited into waterbodies or land, is known to cause a number of adverse effects. Though not quantified here, these effects include IQ loss measured by performance on neurobehavioral tests, particularly on tests of attention, fine motor-function, language, and visual spatial ability.

C. What are the cost impacts?

We estimate the total capital and annualized costs of this final rule for existing sources in the Taconite Iron Ore Processing source category will be approximately $106 million and $68 million per year, respectively. The annual costs are based on operation and maintenance of added control systems. Although this action also finalizes standards for new sources, we are not aware of any new sources being constructed now or planned for the future. No new indurating furnaces have been constructed, reconstructed or modified in more than a decade and the domestic demand for taconite pellets has decreased over the past several decades caused by the increasing use of electric arc furnaces.[7] Consequently, we did not estimate any cost impacts for new sources. The memorandum, *Development of Impacts for the Final Amendments to the NESHAP for Taconite Iron Ore Processing,* includes details of our cost assessment, expected emission reductions and estimated secondary impacts. A copy of this memorandum is available in the docket for this action.

D. What are the economic impacts?

The EPA assessed the potential economic impacts of this action by comparing the expected annual cost for operating the air pollution control devices to the total sales revenue for the ultimate owners of affected facilities. The expected annual cost is $10.2 million (on average) for each facility that needs air pollution controls to comply with the standards, with an estimated nationwide annual cost of $61 million per year. The six affected facilities are owned by two parent companies (U.S. Steel and Cleveland-Cliffs, Inc.). Neither parent company qualifies as a small business, and the total costs associated with this final rule are expected to be less than 1 percent of annual sales revenue per ultimate owner.

The EPA also modeled the economic impacts of the final rule using two standard partial equilibrium economic models: one for taconite iron ore pellets and one for steel mill products. The EPA linked these two partial equilibrium models by specifying interactions between supply and demand in both markets and solving for changes in prices and quantity across both markets simultaneously. These models use baseline economic data from 2019 to project the impact of the final rule on the market for taconite iron ore pellets and steel mill products. The models allow the EPA to project facility- and market-level price and quantity changes for taconite iron ore pellets and market-level price and quantity changes for steel mill products, including changes in imports and exports in both markets. The models project a 0.28 percent fall in the quantity of domestically produced taconite iron ore pellets along with a 0.63 percent increase in their price. The models also project a 0.02 percent fall in the quantity of domestically produced steel mill products along with an 0.01 percent increase in their price. Details of our economic impact estimates for sources in the Taconite Iron Ore Processing source category may be found in the document, *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Amendments* (EIA), which is available in the docket for this action.

E. What analysis of environmental justice did we conduct?

Consistent with the EPA's commitment to integrating environmental justice (EJ) into the Agency's actions, and following the directives set forth in multiple executive orders, the EPA evaluated the impacts of this action on communities with EJ concerns. Overall, we found that in the population living in close proximity (within 10 kilometers (km)) of facilities, the following demographic groups were above the national average: White, Native American, and people living below the poverty level. The EPA defines EJ as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' [8] The EPA further defines fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

For the Taconite Iron Ore Processing source category, the EPA examined the potential for EJ concerns by conducting a proximity demographic analysis for the eight existing taconite iron ore processing plants (seven operating plants and one indefinitely idled). The proximity demographic analysis is an assessment of individual demographic groups in the total population living within 10 km and 50 km of the facilities. The EPA compared the data from this analysis to the national average for each of the demographic groups. Since the taconite iron ore processing facilities are very large, a radius of 10 km was used as the near facility distance for the proximity analysis. A distance closer than 10 km does not yield adequate population size for the results. A summary of the proximity demographic assessment was included in Table 5 in the proposal for this rulemaking (88 FR 30931; May 15, 2023). The results show that for the population living within 10

[5] U.S. EPA, 2022. *Estimating $PM_{2.5}$- and Ozone-Attributable Health Benefits.* Office of Air and Radiation, Research Triangle Park, NC.

[6] U.S. EPA (2023). Technical Support Document Estimating the Benefit per Ton of Reducing Directly-Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impact Division. Available at: *https://www.epa.gov/system/files/documents/2021-10/source-apportionment-tsd-oct-222021_0.pdf.*

[7] U.S. EPA, 2024. *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Amendments.* Office of Air and Radiation, Research Triangle Park, NC.

[8] *https://www.epa.gov/environmentaljustice.*

km of the eight facilities, the following demographic groups were above the national average: White (93 percent versus 60 percent nationally), Native American (0.8 percent versus 0.7 percent nationally), and people living below the poverty level (15 percent versus 13 percent nationally). For two facilities (the UTAC and Minntac facilities), the percentage of the population living within 10 km that is Native American (1.9 percent and 2.3 percent) was more than double the national average (0.7 percent). For four facilities (Keetac, Hibbing, Minorca, and Minntac) the percentage of the population living within 10 km that is low-income is above the national average. The results of the proximity analysis are in the technical report, *Analysis of Demographic Factors For Populations Living Near Taconite Iron Ore Processing Source Category Operations,* which is available in the docket for this action.

This action sets new standards for Hg and revised standards for HCl and HF that will reduce the annual emissions of these HAP from taconite facilities. The Hg standards will reduce the health, environmental and cultural impacts of Hg identified by tribes in their comments by requiring the five taconite facilities (UTAC, Keetac, Hibbing, Minorca, and Minntac) that have nearby Native American populations and low-income populations above the national averages to reduce Hg emissions by up to 247 pounds per year (0.12 tpy). The emission limits must be met at all times (including periods of startup, shutdown, and malfunctions) and compliance must be demonstrated through monitoring of control device operating parameters and either periodic testing or CEMS.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a ''significant regulatory action'' as defined in Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an economic analysis of the potential impacts associated with this action. This analysis is summarized in section IV.D of this preamble and in the document *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Amendments,* available in Docket ID No. EPA–HQ–OAR–2017–0664.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2050.10, OMB Control Number 2060–0538. You can find a copy of the ICR in the docket for this action, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

In this action, we are finalizing changes to the reporting and recordkeeping requirements for the Taconite Iron Ore Processing NESHAP by incorporating reporting and recordkeeping requirements for the new MACT standards for Hg and the revised emission standards for HCl and HF.

Respondents/affected entities: Owners or operators of taconite iron ore plants that are major sources, or that are located at, or are part of, major sources of HAP emissions.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart RRRRR).

Estimated number of respondents: On average over the next 3 years, approximately seven existing major sources will be subject to these standards. It is also estimated that no additional respondent will become subject to the emission standards over the 3-year period.

Frequency of response: The frequency of responses varies depending on the burden item.

Total estimated burden: The average annual burden to industry over the next 3 years from the new recordkeeping and reporting requirements is estimated to be 1,580 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting costs for all facilities to comply with all the requirements in the NESHAP is estimated to be $185,000 per year. The average annual recordkeeping and reporting cost for this rulemaking is estimated to be $26,500 per facility per year. The operation and maintenance costs are estimated to be $18 million per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The Agency confirmed through responses to a CAA section 114 information request that there are only seven taconite iron ore processing plants currently operating in the United States and that these plants are owned by two parent companies that do not meet the definition of small businesses, as defined by the U.S. Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. The Executive Order defines Tribal implications as ''actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' The amendments in this action would not have a substantial direct effect on one or more tribes, change the relationship between the Federal Government and tribes, or affect the distribution of power

and responsibilities between the Federal Government and Indian Tribes. Thus, Executive Order 13175 does not apply to this action.

Although this action does not have Tribal implications as defined by Executive Order 13175, consistent with the *EPA Policy on Consultation and Coordination with Indian Tribes,* the EPA consulted with Tribal officials during the development of this action. On January 12, 2022, the EPA's Office of Air and Radiation held a Tribal consultation meeting with the Fond du Lac Band of Lake Superior Chippewa Reservation and the Leech Lake Band of Ojibwe Reservation to discuss the EPA's 2022 CAA section 114 information request and to ensure that the views of tribes were taken into consideration in the rulemaking process in accordance with the *EPA Policy on Consultation and Coordination with Indian Tribes (May 4, 2011)* and the *EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights (February 2016).* A summary of the meeting may be found in the document, *Consultation with the Fond du Lac Band of Lake Superior Chippewa and the Leech Lake Band of Ojibwe regarding Notice of Proposed Rulemaking for the National Emission Standards for Hazardous Air Pollutants for Taconite Iron Ore Processing Amendments on January 12, 2022,* which is available in the docket for this action. In addition, the EPA's staff attended several meetings hosted by the Minnesota Pollution Control Agency (MPCA), along with representatives from Tribal Nations, MPCA, the Michigan Attorney General's Office, the Minnesota Attorney General's Office, Earthjustice, and the Michigan Department of Environment, Great Lakes, and Energy, to discuss concerns related to HAP emissions from taconite iron ore processing facilities. The EPA also received letters from representatives of the Leech Lake Band of Ojibwe and the Fond du Lac Band of Lake Superior Chippewa expressing concerns of these Tribal Nations due to HAP emissions from the taconite iron ore processing facilities. Copies of these letters, as well as the EPA's responses to them, are available in the docket for this action.

G. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted searches for the Taconite Iron Ore Processing NESHAP through the Enhanced National Standards Systems Network (NSSN) Database managed by the American National Standards Institute (ANSI). We also conducted a review of VCS organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 1A, 2, 2A, 2C, 2D, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 17, 26A, 29 and 30B. During the VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA ordered a copy of the standard and reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering, and policy equivalence to procedures in the EPA referenced methods. The EPA may reconsider determinations of impracticality when additional information is available for any particular VCS.

No VCS were identified for EPA Methods 1, 1A, 2, 2A, 2C, 2D, 2F, 2G, 3, 3A, 4, 5, 5D, 17 or 26A. One VCS was identified as an acceptable alternative to EPA Methods 3B, 29 and 30B.

The EPA is allowing use of the VCS ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)'' as an acceptable alternative to EPA Method 29 (Hg portion only) as a method for measuring Hg concentrations ranging from approximately 0.5 to 100 micrograms per normal cubic meter (μg/Nm^3). This test method describes equipment and procedures for obtaining samples from effluent ducts and stacks, equipment and procedures for laboratory analysis, and procedures for calculating results. VCS ASTM D6784–16 allows for additional flexibility in the sampling and analytical procedures from the earlier version of the same standard VCS ASTM D6784–02 (Reapproved 2008). VCS ASTM D6784–16 allows for the use of either an EPA Method 17 sampling configuration with a fixed (single) point where the flue gas is not stratified, or an EPA Method 5 sampling configuration with a multi-point traverse. For this action, only the EPA Method 5 sampling configuration with a multi-point traverse can be used. This method is available at ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959. See *https://www.astm.org/*. The standard is available to everyone at a cost determined by ASTM ($82). The cost of obtaining this method is not a significant financial burden, making the method reasonably available. Additional detailed information on the VCS search and determination can be found in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing,* which is available in the docket for this action. The EPA solicited comment on potentially applicable VCS in the proposal for this rule. However, no other VCS were identified. The EPA is finalizing as proposed incorporating by reference the VCS ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method),'' as an acceptable alternative to EPA Method 29 (Hg portion only).

H. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. The assessment of populations in close proximity of taconite iron ore processing plants shows Native American and low-income populations are higher than the national average (see section IV.E of this preamble). The higher percentages of Native American populations are near the UTAC and Minntac facilities. The higher percentages of low-income populations are near the Keetac, Hibbing, Minorca, and Minntac facilities. The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on low-income populations and/or indigenous peoples. The EPA is finalizing new MACT standards for Hg and revised standards for HCl and HF. The EPA expects that at least five facilities would have to implement control measures to reduce Hg emissions to comply with the new Hg MACT standard (including the UTAC, Keetac, Hibbing, Minorca and Minntac facilities) and one facility would need to implement control measures to reduce HCl emissions to comply with the revised standard for HCl (the Tilden facility). HAP exposures for indigenous peoples and low-income individuals

living near these six facilities would decrease. The methodology and the results of the demographic analysis are available in the docket for this action in the technical report *Analysis of Demographic Factors For Populations Living Near Taconite Iron Ore Processing Source Category Operations.*

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885; April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not significant as defined in Executive Order 12866(3)(f)(1), and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. In 2020, the EPA conducted a residual risk assessment and determined that risk from the Taconite Iron Ore Processing source category was acceptable, and the standards provided an ample margin of safety to protect public health (see 85 FR 45476 and Docket ID No. EPA–HQ–OAR–2017–0664–0163). For this rulemaking, we updated that risk analysis using new emissions data that the EPA received for some HAP emissions sources at the taconite facilities. We determined that these new HAP emissions estimates would not significantly change our previous estimates of the human health risk posed by the Taconite Iron Ore Processing source category. In this action the EPA is promulgating new emission standards for one previously unregulated pollutant (Hg) and revised emissions standards for two currently regulated pollutants (HCl and HF). These emissions standards will reduce Hg, HCl and HF emissions and thereby reduce children's exposure to these harmful HAP. We estimate that the installation of controls will reduce HCl and HF emissions by 683 tpy and 36 tpy, respectively, and will reduce Hg emissions by up to 247 pounds per year (0.12 tpy).

This action's health and risk assessments are protective of the most vulnerable populations, including children, due to how we determine exposure and through the health benchmarks that we use. Specifically, the risk assessments we perform assume a lifetime of exposure, in which populations are conservatively presumed to be exposed to airborne concentrations at their residence continuously, 24 hours per day for a 70-year lifetime, including childhood. With regards to children's potentially greater susceptibility to noncancer toxicants, the assessments rely on the EPA's (or comparable) hazard identification and dose-response values that have been developed to be protective for all subgroups of the general population, including children. For more information on the risk assessment methods, see the risk report for the July 28, 2020, final Taconite residual risk and technology review (RTR) rule (85 FR 45476), which is available in the docket. Therefore, the rulemaking finalizes actions that will result in health benefits to children by reducing the level of HAP emissions emitted from taconite iron ore processing plants.

J. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. We have concluded that this action is not likely to have any adverse energy effects because it contains no regulatory requirements that will have an adverse impact on productivity, competition, or prices in the energy sector.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, air pollution control, hazardous substances, incorporation by reference, mercury, hydrogen chloride, hydrogen fluoride, reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—General Provisions

■ 2. Section 63.14 is amended by revising paragraph (i)(104) to read as follows:

§ 63.14 Incorporation by reference

* * * * *

(i) * * *

(104) ASTM D6784–16, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), Approved March 1, 2016; IBR approved for §§ 63.9621(d); table 5 to subpart UUUUU; appendix A to subpart UUUUU.

Subpart RRRRR—National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing

■ 3. Section 63.9583 is revised and republished to read as follows:

§ 63.9583 When do I have to comply with this subpart?

(a) If you have an existing affected source, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you no later than October 30, 2006, except as specified in paragraph (f) of this section.

(b) If you have a new affected source and its initial startup date is on or before October 30, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you by October 30, 2003, except as specified in paragraph (f) of this section.

(c) If you have a new affected source and its initial startup date is after October 30, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you upon initial startup, except as specified in paragraph (f) of this section.

(d) If your taconite iron ore processing plant is an area source that becomes a major source of HAP, the compliance dates in paragraphs (d)(1) and (2) of this section apply to you.

(1) Any portion of the taconite iron ore processing plant that is a new affected source or a new reconstructed source must be in compliance with this subpart upon startup.

(2) All other parts of the taconite iron ore processing plant must be in compliance with this subpart no later than 3 years after the plant becomes a major source.

(e) You must meet the notification and schedule requirements in § 63.9640. Several of these notifications must be submitted before the compliance date for your affected source.

(f) If you have an affected indurating furnace that commenced construction before May 15, 2023, you must comply with the requirements in paragraphs (f)(1) through (7) of this section by March 8, 2027. If you have an affected indurating furnace that commenced construction or reconstruction on or after May 15, 2023, you must comply with the requirements in paragraphs (f)(1) through (7) of this section by March 6, 2024 or the date of initial startup, whichever is later.

(1) All applicable emission limits for mercury, hydrogen chloride, and hydrogen fluoride in tables 2 and 3 to this subpart.

(2) All applicable operating limits in § 63.9590(b)(5) through (8), established in accordance with § 63.9622(g) through (i), for each control device used to comply with the mercury, hydrogen chloride, and hydrogen fluoride emission limits.

(3) All applicable compliance requirements in §§ 63.9600, 63.9610, 63.9623, 63.9625, and 63.9637(a).

(4) The applicable performance testing or continuous emissions monitoring system (CEMS) requirements for mercury in §§ 63.9620(k), 63.9621(d), and 63.9630.

(5) All applicable performance testing requirements in §§ 63.9620(l), 63.9621(d), and 63.9630.

(6) The requirements to install and maintain monitoring equipment in § 63.6332(g) through (i) and the monitoring requirements in §§ 63.9631, 63.9633, and 63.9634 for each control device used to comply with the mercury, hydrogen chloride and hydrogen fluoride emission limits.

(7) The notification, reporting and recordkeeping requirements in §§ 63.9640, 63.9641, 63.9642, and 63.9643 applicable to the mercury, hydrogen chloride, and hydrogen fluoride emission standards.

■ 4. Section 63.9590 is revised and republished to read as follows:

§ 63.9590 What emission limitations and operating limits must I meet?

(a) You must meet each emission limit in tables 1 through 3 to this subpart that applies to you by the applicable compliance date specified in § 63.9583.

(b) You must meet each applicable operating limit for control devices in paragraphs (b)(1) through (8) of this section that applies to you by the applicable compliance date specified in § 63.9583. You are not required to establish and comply with operating limits for control devices used to reduce mercury emissions when you are using a CEMS to monitor and demonstrate compliance with the mercury emission limit in table 2 to this subpart.

(1) Except as provided in paragraph (b)(2) of this section, for each wet scrubber applied to meet any particulate matter emission limit in table 1 to this subpart, you must maintain the daily average pressure drop and daily average scrubber water flow rate at or above the minimum levels established in § 63.9622.

(2) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, for each dynamic wet scrubber applied to meet any particulate matter emission limit in table 1 to this subpart, you must maintain the daily average scrubber water flow rate and either the daily average fan amperage (a surrogate for fan speed as revolutions per minute) or the daily average pressure drop at or above the minimum levels established during the initial performance test. After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, for each dynamic wet scrubber applied to meet any particulate matter emission limit in table 1 to this subpart, you must maintain the daily average scrubber water flow rate and the daily average fan amperage (a surrogate for fan speed as revolutions per minute) at or above the minimum levels established in § 63.9622.

(3) For each dry electrostatic precipitator (ESP) applied to meet any particulate matter emission limit in Table 1 to this subpart, you must meet the operating limits in paragraph (b)(3)(i) or (ii) of this section.

(i) Maintain the 6-minute average opacity of emissions exiting the control device stack at or below the level established during the initial performance test.

(ii) Maintain the daily average secondary voltage and daily average secondary current for each field at or above the minimum levels established during the initial performance test.

(4) For each wet ESP applied to meet any particulate matter emission limit in table 1 to this subpart, you must meet the operating limits in paragraphs (b)(4)(i) through (iii) of this section.

(i) Maintain the daily average secondary voltage for each field at or above the minimum levels established during the initial performance test.

(ii) Maintain the daily average stack outlet temperature at or below the maximum levels established during the initial performance test.

(iii) Maintain the daily average water flow rate at or above the minimum levels established during the initial performance test.

(5) For each wet scrubber and wet ESP used to meet the hydrogen chloride and hydrogen fluoride emission limits in table 3 to this subpart, you must maintain the daily average scrubber water flow rate and pH greater than or equal to the operating limits established for these parameters established in § 63.9622.

(6) For each activated carbon injection (ACI) system used to meet the mercury emission limit in table 2 to this subpart, you must maintain the daily average activated carbon injection rate greater than or equal to the average activated carbon injection rate established during the most recent performance test demonstrating compliance with the applicable emission limit. In addition, you must maintain the daily average carrier gas flow rate greater than or equal to the average carrier gas flow rate established during the most recent performance test demonstrating compliance with the applicable emission limit.

(7) For each dry sorbent injection (DSI) system used to meet the hydrogen chloride and hydrogen fluoride emission limits in table 3 to this subpart, you must maintain the daily average dry sorbent injection rate greater than or equal to the average dry sorbent injection rate established during the most recent performance test. demonstrating compliance with the applicable emission limit. In addition, you must maintain the daily average carrier gas flow rate greater than or equal to the average carrier gas flow rate established during the most recent performance test demonstrating compliance with the applicable emission limit.

(8) If you use any air pollution control device other than a baghouse, wet scrubber, dynamic scrubber, dry ESP, wet ESP, ACI, or DSI, you must submit a site-specific monitoring plan in accordance with § 63.9631(f).

(c) You may petition the Administrator for approval of alternatives to the monitoring requirements in paragraphs (b)(1) through (7) of this section as allowed under § 63.8(f) and as defined in § 63.90.

■ 5. Section 63.9600 is amended by revising paragraph (b) introductory text to read as follows:

§ 63.9600 What are my operation and maintenance requirements?

* * * * *

(b) You must prepare, and at all times, operate according to, a written operation and maintenance plan for each control device applied to meet any particulate matter emission limit in table 1 to this subpart, mercury emission limit in table 2 to this subpart, hydrogen chloride and hydrogen fluoride emission limit in table 3 to this subpart, and to meet the requirement of each indurating furnace subject to good combustion practices (GCP). Each site-specific operation and maintenance plan must be submitted to the Administrator on or before the compliance date that is specified in § 63.9583 for your affected source. The plan you submit must explain why the chosen practices (*i.e.,* quantified objectives) are effective in performing corrective actions or GCP in minimizing the formation of formaldehyde (and other products of incomplete combustion). The Administrator will review the adequacy of the site-specific practices and objectives you will follow and the records you will keep to demonstrate compliance with your Plan. If the Administrator determines that any portion of your operation and maintenance plan is not adequate, we can reject those portions of the plan, and request that you provide additional information addressing the relevant issues. In the interim of this process, you will continue to follow your current site-specific practices and objectives, as submitted, until your revisions are accepted as adequate by the Administrator. You must maintain a current copy of the operation and maintenance plan onsite, and it must be available for inspection upon request. You must keep the plan for the life of the affected source or until the affected source is no longer subject to the requirements of this subpart. Each operation and maintenance plan must address the elements in paragraphs (b)(1) through (4) of this section.

* * * * *

■ 6. Section 63.9610 is amended by revising paragraph (a) introductory text and adding paragraph (d) to read as follows:

§ 63.9610 What are my general requirements for complying with this subpart?

(a) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, you must be in compliance with the requirements in paragraphs (a)(1) through (6) of this section at all times, except during periods of startup, shutdown, and malfunction. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, for affected sources that commenced construction or reconstruction after September 25, 2019, you must be in compliance with the emission limitations, standards, and operation and maintenance requirements for the particulate matter emission standards in this subpart at all times.

* * * * *

(d) On and after the applicable compliance date specified in § 63.9583(f), you must be in compliance with all applicable emission limitations for mercury, hydrogen chloride and hydrogen fluoride in tables 2 and 3 to this subpart and with the requirements in paragraphs (d)(1) through (6) of this section at all times.

(1) All applicable operating limits in § 63.9590(b)(5) through (8).

(2) All applicable operation and maintenance requirements in § 63.9600 for control devices and monitoring equipment used to comply with the emissions limits.

(3) The requirements in § 63.9631(j), if you use emissions averaging to demonstrate compliance with the mercury standards.

(4) The requirements in § 63.9631(k), if you use continuous emissions monitoring system(s) (CEMS) to demonstrate compliance with the mercury standards.

(5) The requirements in § 63.9634(n), if you elect to adjust the activated carbon injection rate based on the taconite pellet production rate.

(6) The notification, reporting and recordkeeping requirements in §§ 63.9640 through 63.9643.

■ 7. Section 63.9620 is amended by:

■ a. Revising paragraphs (b)(2) and (f)(2); and

■ b. Adding paragraphs (k) and (l).

The revisions and addition read as follows:

§ 63.9620 On which units and by what date must I conduct performance tests or other initial compliance demonstrations?

* * * * *

(b) * * *

(2) Initial performance tests must be completed no later than 180 calendar days after the compliance date specified in § 63.9583. Performance tests conducted between October 30, 2003, and no later than 180 days after the corresponding compliance date can be used for initial compliance demonstration, provided the tests meet the initial performance testing requirements of this subpart. For an indurating furnace with multiple stacks, the performance tests for all stacks must be completed within 7 calendar days of commencement of the performance tests, to the extent practicable, and the indurating furnace and associated control device (where applicable) operating characteristics must remain representative and consistent for the duration of the stack tests. If you determine that the performance tests cannot be completed within 7 calendar days, the Administrator must be notified within 24 hours of making that determination.

* * * * *

(f) * * *

(2) All emission units within a group must also have the same type of air pollution control device (*e.g.,* wet scrubbers, dynamic wet scrubbers, rotoclones, multiclones, wet and dry ESP, and baghouses). You cannot group emission units with different air pollution control device types together for the purposes of this section.

* * * * *

(k) For each indurating furnace, you must demonstrate initial compliance with the mercury emission limits in table 2 to this subpart in accordance with the procedures specified in either paragraph (k)(1) or (2) of this section.

(1) Complete an initial performance test on all stacks associated with each indurating furnace no later than 180 calendar days after the compliance date specified in § 63.9583(f). Performance tests conducted between March 6, 2024 and 180 days after the corresponding compliance date can be used for initial compliance demonstration, provided the tests meet the initial performance testing requirements of this subpart. For an indurating furnace with multiple stacks, the performance tests for all stacks must be completed within 7 calendar days of commencement of the performance tests, to the extent practicable, and the indurating furnace and associated control device (where applicable) operating characteristics must remain representative and consistent for the duration of the stack tests. If you determine that the performance tests cannot be completed within 7 calendar days, the Administrator must be notified within 24 hours of making that determination.

(2) You may use a 30-day rolling average of the 1-hour arithmetic average CEMS data. You must conduct a performance evaluation of each CEMS within 180 days of installation of the monitoring system. The initial performance evaluation must be conducted prior to collecting CEMS data

that will be used for the initial compliance demonstration.

(l) For each indurating furnace, you must demonstrate initial compliance with the emission limits in table 3 to this subpart by conducting initial performance tests for hydrogen chloride and hydrogen fluoride on all stacks associated with each indurating furnace. Initial performance tests must be completed no later than 180 calendar days after the compliance date specified in § 63.9583(f). Performance tests conducted between March 6, 2024 and 180 days after the corresponding compliance date can be used for initial compliance demonstration, provided the tests meet the initial performance testing requirements of this subpart. For an indurating furnace with multiple stacks, the performance tests for all stacks must be completed within 7 calendar days of commencement of the performance tests, to the extent practicable, and the indurating furnace and associated control device (where applicable) operating characteristics must remain representative and consistent for the duration of the stack tests. If you determine that the performance tests cannot be conducted within 7 calendar days, the Administrator must be notified within 24 hours of making that determination.

■ 8. Section 63.9621 is amended by:
■ a. Revising the section heading;
■ b. Revising paragraphs (a) and (c) introductory text; and
■ c. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 63.9621 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits?

(a) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, you must conduct each performance test that applies to your affected source according to the requirements in § 63.7(e)(1) and paragraphs (b) and (c) of this section. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, you must conduct each performance test that applies to your affected source, including the initial performance tests for mercury required in § 63.9620(k)(1) and the initial performance tests for hydrogen chloride and hydrogen fluoride required in § 63.9620(l), under normal operating conditions of the affected source. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. You must also conduct each performance test that applies to your affected source according to the requirements in paragraphs (b) and (c) of this section.

* * * * *

(c) For each ore dryer affected source and each indurating furnace affected source, you must determine compliance with the applicable emission limit for particulate matter in table 1 to this subpart by following the test methods and procedures in paragraphs (c)(1) through (2) of this section.

* * * * *

(d) For each indurating furnace subject to the initial performance testing under § 63.9620(k)(1) or (l), you must determine compliance with the applicable emission limits for mercury, hydrogen chloride and hydrogen fluoride in tables 2 and 3 to this subpart by following the test methods and procedures in paragraphs (d)(1) through (9) of this section. You are not required to complete the initial performance test for mercury emissions when you are using a CEMS in accordance with paragraph (e) of this section.

(1) The furnace must be operated at or above 90 percent of capacity throughout the duration of the performance testing. If testing cannot be performed at or above 90 percent of capacity, you must provide an explanation for the lower production rate in your performance test plan. The lower production rate must be approved by the Administrator prior to beginning performance testing. For indurating furnaces that comply with the mercury emissions limit in table 2 to this subpart by adjusting the activated carbon injection rate based on the taconite pellet production rate, you must complete the performance testing for mercury in accordance with the provisions in § 63.9634(n).

(2) Use the methods specified in paragraphs (c)(1)(i) through (iv) of this section to select sampling port locations and the number of traverse points and to determine the volumetric flow rate, dry molecular weight, and moisture content of the stack gas.

(3) Determine the concentration of mercury for each stack using Method 29 or Method 30B in 40 CFR part 60, appendix A, or the voluntary consensus standard ASTM D6784–16 (incorporated by reference, see § 63.14). For Method 29 and ASTM D6784–16, the sample volume must be at least 1.7 dry standard cubic meters (dscm) (60 dry standard cubic feet) per run. For Method 30B, each test run must be at least one hour in duration.

(4) Determine the concentration of hydrogen chloride and hydrogen fluoride for each stack using Method 26A in 40 CFR part 60, appendix A. Each test must consist of three separate runs. The minimum sample volume must be at least 2 dscm per run.

(5) During each stack test run, determine the weight of taconite pellets produced and calculate the emissions rate of each pollutant in pounds of pollutant per long ton (lb/LT) of pellets produced for each test run. The weight of taconite pellets produced must be determined by measurement using weigh hoppers, belt weigh feeders, or weighed quantities in shipments, or calculated using the bulk density and volume measurements. If any measurement result for any pollutant is reported as below the method detection limit, use the method detection limit as the measured emissions level for that pollutant when calculating the emission rate. If the furnace has more than one stack, calculate the total emissions rate for each test run by summing the emissions across all stacks, as shown in Equation 4.

$$E_{f,i} = \sum_{s=1}^{n} \frac{C_s \times Q_s}{P_f} \quad (Eq. 4)$$

Where:

$E_{f,i}$ = Emissions rate for test run ''i'' for all emission stacks on indurating furnace ''f'', lb/LT of pellets produced,

C_s = Emission rate for stack ''s'' measured during test run ''i'' on indurating furnace ''f'', lb/dscf,

Q_s = Average volumetric flow rate of stack gas measured at stack ''s'' during test run ''i'' on indurating furnace ''f'', dscf/hour;

P_f = Pellets produced in indurating furnace ''f'' during the stack test, LT; and

n = Number of emissions stacks on furnace ''f''.

(6) Calculate the average emissions rate for each furnace using the three test runs, as show in Equation 5 of this section.

$$E_f = \frac{E_1 + E_2 + E_3}{3} \quad (Eq. 5)$$

Where:

E_f = Average emission rate for indurating furnace ''f'', lb/LT of pellets produced,
E_1 = Emissions rate for run 1 for indurating furnace ''f'', lb/LT of pellets produced,
E_2 = Emissions rate for run 2 for indurating furnace ''f'', lb/LT of pellets produced, and
E_3 = Emissions rate for run 3 for indurating furnace ''f'', lb/LT of pellets produced.

(7) For each indurating furnace constructed or reconstructed on or after May 15, 2023, determine compliance with the applicable mercury emission limit in table 2 to this subpart by calculating the average emissions rate from the three test runs performed on the furnace using Equations 4 and 5 of this section.

(8) For each indurating furnace constructed or reconstructed before May 15, 2023, you must determine compliance with the applicable mercury emission limit in accordance with the procedures specified in either paragraph (d)(8)(i) or (ii) of this section.

(i) Determine compliance with the mercury limit for individual furnaces in table 2 to this subpart by calculating the average mercury emissions rate for each affected indurating furnace using Equations 4 and 5 of this section, or

(ii) Determine compliance with the mercury limit for groups of indurating furnaces in table 2 to this subpart in accordance with the method in § 63.9623(d).

(9) Determine compliance with the applicable hydrogen chloride and hydrogen fluoride emission limits in table 3 to this subpart by calculating the average emissions rate for each indurating furnace for the three test runs performed on the furnace using Equations 4 and 5 of this section.

(e) For each indurating furnace using mercury CEMS to demonstrate compliance with the applicable emission limits for mercury, you must determine compliance with the applicable mercury limit in table 2 to this subpart by using a 30-day rolling average of the 1-hour arithmetic average CEMS data, including CEMS data during startup and shutdown as defined in this subpart. The mercury CEMS must be installed, calibrated, maintained, and operated as accordance with the requirements in § 63.9631(j).

■ 9. Section 63.9622 is revised and republished to read as follows:

§ 63.9622 What test methods and other procedures must I use to establish and demonstrate initial compliance with the operating limits?

(a) For wet scrubbers subject to performance testing in § 63.9620 and operating limits for pressure drop and scrubber water flow rate in § 63.9590(b)(1), you must establish site-specific operating limits according to the procedures in paragraphs (a)(1) through (3) of this section.

(1) Using the CPMS required in § 63.9631(b), measure and record the pressure drop and scrubber water flow rate every 15 minutes during each run of the particulate matter performance test.

(2) Calculate and record the average pressure drop and scrubber water flow rate for each individual test run. Your operating limits are established as the lowest average pressure drop and the lowest average scrubber water flow rate corresponding to any of the three test runs, except as specified in paragraph (g)(2) of this section.

(3) If a rod-deck venturi scrubber is applied to an indurating furnace to meet any particulate matter emission limit in table 1 to this subpart, you may establish a lower average pressure drop operating limit by using historical average pressure drop data from a certified performance test completed on or after December 18, 2002 instead of using the average pressure drop value determined during the initial performance test, as specified in paragraph (a)(2) of this section. If historical average pressure drop data are used to establish an operating limit (*i.e.,* using data from a certified performance test conducted prior to the promulgation date of the final rule), then the average particulate matter concentration corresponding to the historical performance test must be at or below the applicable indurating furnace emission limit, as listed in table 1 to this subpart.

(b) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, for dynamic wet scrubbers subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and either fan amperage or pressure drop in § 63.9590(b)(2), you must establish site-specific operating limits according to the procedures in paragraphs (b)(1) and (2) of this section. After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, for dynamic wet scrubbers subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and fan amperage in § 63.9590(b)(2), you must establish site-specific operating limits according to the procedures in paragraphs (b)(1) and (2) of this section.

(1) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, using the CPMS required in § 63.9631(b), measure and record the scrubber water flow rate and either the fan amperage or pressure drop every 15 minutes during each run of the particulate matter performance test. After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, using the CPMS required in § 63.9631(b), measure and record the scrubber water flow rate and the fan amperage every 15 minutes during each run of the particulate matter performance test.

(2) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, calculate and record the average scrubber water flow rate and either the average fan amperage or the average pressure drop for each individual test run. Your operating limits are established as the lowest average scrubber water flow rate and either the lowest average fan amperage or pressure drop value corresponding to any of the three test runs. After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, calculate and record the average scrubber water flow rate and the average fan amperage for each individual test run. Your operating limits are established as the lowest average scrubber water flow rate and the lowest average fan amperage value corresponding to any of the three test runs, except as specified in paragraph (g)(2) of this section.

(c) For a dry ESP subject to performance testing in § 63.9620 and operating limits in § 63.9590(b)(3), you must establish a site-specific operating limit according to the procedures in paragraphs (c)(1) or (2) of this section.

(1) If the operating limit for your dry ESP is a 6-minute average opacity of emissions value, then you must follow the requirements in paragraphs (c)(1)(i) through (iii) of this section.

(i) Using the continuous opacity monitoring system (COMS) required in § 63.9631(d)(1), measure and record the opacity of emissions from each control device stack during the particulate matter performance test.

(ii) Compute and record the 6-minute opacity averages from 24 or more data points equally spaced over each 6-minute period (*e.g.,* at 15-second intervals) during the test runs.

(iii) Using the opacity measurements from a performance test that meets the emission limit, determine the opacity value corresponding to the 99 percent upper confidence level of a normal distribution of the 6-minute opacity averages.

(2) If the operating limit for your dry ESP is the daily average secondary voltage and daily average secondary current for each field, then you must follow the requirements in paragraphs (c)(2)(i) and (ii) of this section.

(i) Using the CPMS required in § 63.9631(d)(2), measure and record the secondary voltage and secondary current for each dry ESP field every 15 minutes during each run of the particulate matter performance test.

(ii) Calculate and record the average secondary voltage and secondary current for each dry ESP field for each individual test run. Your operating limits are established as the lowest average secondary voltage and secondary current value for each dry ESP field corresponding to any of the three test runs.

(d) For a wet ESP subject to performance testing in § 63.9620 and operating limit in § 63.9590(b)(4), you must establish a site-specific operating limit according to the procedures in paragraphs (d)(1) and (2) of this section.

(1) Using the CPMS required in § 63.9631(e), measure and record the parametric values in paragraphs (d)(1)(i) through (iii) of this section for each wet ESP field every 15 minutes during each run of the particulate matter performance test.

(i) Secondary voltage;

(ii) Water flow rate; and

(iii) Stack outlet temperature.

(2) For each individual test run, calculate and record the average value for each operating parameter in paragraphs (d)(1)(i) through (iii) of this section for each wet ESP field. Your operating limits are established as the lowest average value for each operating parameter of secondary voltage and water flow rate corresponding to any of the three test runs, and the highest average value for each stack outlet temperature corresponding to any of the three test runs.

(e) If you use an air pollution control device other than a wet scrubber, dynamic wet scrubber, dry ESP, wet ESP, or baghouse, and it is subject to performance testing in § 63.9620, you must submit a site-specific monitoring plan in accordance with § 63.9631(f). The site-specific monitoring plan must include the site-specific procedures for demonstrating initial and continuous compliance with the corresponding operating limits.

(f) You may change the operating limits for any air pollution control device as long as you meet the requirements in paragraphs (f)(1) through (3) of this section.

(1) Submit a written notification to the Administrator of your request to conduct a new performance test to revise the operating limit.

(2) Conduct a performance test to demonstrate compliance with the applicable emission limitation in table 1 to this subpart.

(3) Establish revised operating limits according to the applicable procedures in paragraphs (a) through (e) of this section.

(g) For wet scrubbers and wet ESPs subject to performance testing in § 63.9620(l) and operating limits for scrubber water flow rate and pH in § 63.9590(b)(5), you must establish site-specific operating limits according to the procedures in paragraphs (g)(1) and (2) of this section.

(1) Using the CPMS required in § 63.9631(b), measure and record the scrubber water flow rate and pH of the scrubber water effluent every 15 minutes during each run of the performance test for hydrogen chloride and hydrogen fluoride.

(2) Calculate and record the average scrubber water flow rate and average pH of the scrubber water effluent for each individual test run. Your operating limit must be established as the average scrubber water flow rate and average pH of the scrubber water of the three test runs. If a higher average flow rate is measured during the most recent PM performance test, the operating limit for the daily average scrubber water flow rate is the average scrubber water flow rate measured during the most recent PM performance test. If a higher average flow rate is measured during the most recent HCl and HF performance test, the operating limit for the daily average scrubber water flow rate is the average scrubber water flow rate measured during the most recent HCl and HF performance test.

(h) For ACI systems subject to performance testing in § 63.9620(k)(1) and operating limits for activated carbon sorbent injection rate and carrier gas flow rate in § 63.9590(b)(6), you must establish site-specific operating limits according to the procedures in paragraphs (h)(1) and (2) of this section.

(1) Using the CPMS required in § 63.9631(b), measure and record the activated carbon injection rate and carrier gas flow rate every 15 minutes during each run of the performance test for mercury.

(2) Calculate and record the average activated carbon injection rate and carrier gas flow rate for each individual test run. Your operating limit must be established as the highest activated carbon injection rate and carrier gas flow rate of the three test runs.

(i) For DSI systems subject to performance testing in § 63.9620(l) and operating limits for sorbent injection rate and carrier gas flow rate in § 63.9590(b)(7), you must establish site-specific operating limits according to the procedures in paragraphs (i)(1) and (2) of this section.

(1) Using the CPMS required in § 63.9631(b), measure and record the sorbent injection rate and carrier gas flow rate every 15 minutes during each run of the performance test for hydrogen chloride and hydrogen fluoride.

(2) Calculate and record the average sorbent injection rate and carrier gas flow rate for each individual test run. Your operating limit must be established as the highest average sorbent injection rate and carrier gas flow rate of the three test runs.

■ 10. Section 63.9623 is revised and republished to read as follows:

§ 63.9623 How do I demonstrate initial compliance with the emission limitations that apply to me?

(a) For each affected source subject to an emission limit in tables 1 through 3 to this subpart, you must demonstrate initial compliance by meeting the emission limit requirements in paragraphs (a)(1) through (8) of this section by the compliance date specified in § 63.9583.

(1) For ore crushing and handling, the flow-weighted mean concentration of particulate matter, determined according to the procedures in §§ 63.9620(a) and 63.9621(b), must not exceed the emission limits in table 1 to this subpart.

(2) For indurating furnaces, the flow-weighted mean concentration of particulate matter, determined according to the procedures in §§ 63.9620(b) and 63.9621(c), must not exceed the emission limits in table 1 to this subpart.

(3) For finished pellet handling, the flow-weighted mean concentration of particulate matter, determined according to the procedures in §§ 63.9620(c) and 63.9621(b), must not exceed the emission limits in table 1 to this subpart.

(4) For ore dryers, the flow-weighted mean concentration of particulate matter, determined according to the

procedures in §§ 63.9620(d) and 63.9621(c), must not exceed the emission limits in table 1 to this subpart.

(5) For indurating furnaces not using emissions averaging, the mercury emissions determined according to the procedures in §§ 63.9620(k)(1) or (2) and 63.9621(d), must not exceed the applicable emission limit in table 2 to this subpart.

(6) For indurating furnaces that comply with the mercury emissions limit using emissions averaging, the average mercury emissions determined according to the procedures in §§ 63.9620(k)(1) or (2), 63.9621(d) and 63.9634(m), must not exceed the applicable emission limit in table 2 to this subpart.

(7) For indurating furnaces that comply with the mercury emissions limit by adjusting the activated carbon injection rate based on the taconite pellet production rate, the mercury emissions determined according to the procedures in §§ 63.9620(k)(1) or (2), 63.9621(d) or (e), and 63.9634(n), must not exceed the applicable emission limit in table 2 to this subpart.

(8) For indurating furnaces, the hydrogen chloride and hydrogen fluoride emissions determined according to the procedures in §§ 63.9620(l) and 63.9621(d), must not exceed the applicable emission limit in table 3 to this subpart.

(b) For each affected source subject to an emission limit in table 1 to this subpart, you must demonstrate initial compliance by meeting the operating limit requirements in paragraphs (b)(1) through (5) of this section.

(1) For each wet scrubber subject to performance testing in § 63.9620 and operating limits for pressure drop and scrubber water flow rate in § 63.9590(b)(1), you have established appropriate site-specific operating limits and have a record of the pressure drop and scrubber water flow rate measured during the performance test in accordance with § 63.9622(a).

(2) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, for each dynamic wet scrubber subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and either fan amperage or pressure drop in § 63.9590(b)(2), you have established appropriate site-specific operating limits and have a record of the scrubber water flow rate and either the fan amperage or pressure drop value, measured during the performance test in accordance with § 63.9622(b). After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, for each dynamic wet scrubber subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and fan amperage in § 63.9590(b)(2), you have established appropriate site-specific operating limits and have a record of the scrubber water flow rate and the fan amperage value, measured during the performance test in accordance with § 63.9622(b).

(3) For each dry ESP subject to performance testing in § 63.9620 and one of the operating limits in § 63.9590(b)(3), you must meet the requirements in paragraph (b)(3)(i) or (ii) of this section.

(i) If you are subject to the operating limit for opacity in § 63.9590(b)(3)(i), you have established appropriate site-specific operating limits and have a record of the opacity measured during the performance test in accordance with § 63.9622(c)(1).

(ii) If you are subject to the operating limit for secondary voltage and secondary current in § 63.9590(b)(3)(ii), you have established appropriate site-specific operating limits and have a record of the secondary voltage and secondary current measured during the performance test in accordance with § 63.9622(c)(2).

(4) For each wet ESP subject to performance testing in § 63.9620 and operating limits for secondary voltage, water flow rate, and stack outlet temperature in § 63.9590(b)(4), you have established appropriate site-specific operating limits and have a record of the secondary voltage, water flow rate, and stack outlet temperature measured during the performance test in accordance with § 63.9622(d).

(5) For other air pollution control devices subject to performance testing in § 63.9620 and operating limits in accordance with § 63.9590(b)(8), you have submitted a site-specific monitoring plan in accordance with § 63.9631(f) and have a record of the site-specific operating limits as measured during the performance test in accordance with § 63.9622(e).

(c) Except as specified in paragraph (e) of this section, you must demonstrate initial compliance with the emission limits in tables 2 and 3 to this subpart, by meeting the operating limit requirements in paragraphs (c)(1) through (3) of this section.

(1) For each wet scrubber and wet ESP subject to performance testing in § 63.9620(k) and operating limits for scrubber water flow rate and pH in § 63.9590(b)(5), you have established appropriate site-specific operating limits and have a record of the scrubber water flow rate and pH measured during the performance test in accordance with § 63.9622(g).

(2) For each ACI subject to performance testing in § 63.9620(k) and operating limits for activated carbon injection rate and carrier gas flow rate in § 63.9590(b)(6), you have established appropriate site-specific operating limits and have a record of the activated carbon injection rate and carrier gas flow rate measured during the performance test in accordance with § 63.9622(i).(3) For each DSI subject to performance testing in § 63.9620(k) and operating limits for sorbent injection rate and carrier gas flow rate in § 63.9590(b)(7), you have established appropriate site-specific operating limit and have a record of the sorbent injection rate and carrier gas flow rate measured during the performance test in accordance with § 63.9622(h).

(d) If you elect to comply with the mercury limit in table 2 to this subpart using emissions averaging for indurating furnaces constructed or reconstructed before May 15, 2023, you must comply with the requirements in paragraphs (d)(1) through (4) of this section.

(1) Before submitting the implementation plan required in paragraph (d)(3) of this section, you must complete the mercury stack testing required in § 63.9620(k)(1) or install, calibrate, and operate a mercury CEMS pursuant to § 63.9620(k)(2) and paragraph (e) of this section for all indurating furnaces you wish to include in the mercury emission average.

(2) You must develop and submit to the applicable regulatory authority for review and approval, an implementation plan for mercury emission averaging no later than 180 days before the date you intend to demonstrate compliance using the emission averaging option. You must include the information contained in paragraphs (d)(2)(i) through (iii) of this section in your implementation plan.

(i) Identification of all indurating furnaces in the averaging group, including the typical taconite pellet production rate, control technology installed, and types of fuel(s) that will be burned.

(ii) The mercury emission rate for each furnace for each of the fuels identified in paragraph (d)(2)(i) of this section.

(iii) The date on which you are requesting emission averaging to commence.

(3) The regulatory authority shall review and approve or disapprove the plan according to the following criteria:

(i) Whether the content of the plan includes all the information specified in paragraph (d)(2) of this section, and

(ii) Whether the plan presents sufficient information to determine that compliance will be achieved and maintained.

(4) The applicable regulatory authority shall not approve an emission averaging implementation plan containing any of the following provisions:

(i) Averaging that includes indurating furnaces constructed or reconstructed on or after May 15, 2023, or

(ii) Averaging between indurating furnaces located at different facilities.

(e) If you elect to demonstrate compliance with the mercury limit in table 2 to this subpart using a mercury CEMS, you must calculate the 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at appendix A–7 of 40 CFR part 60. The 1-hour arithmetic averages for CEMS must be calculated using the data points required under § 63.8(c)(4)(ii).

(f) For each emission limitation and operating limit that applies to you, you must submit a notification of compliance status according to § 63.9640(e)

■ 11. Section 63.9630 is amended by revising paragraphs (b) and (e)(2) to read as follows:

§ 63.9630 When must I conduct subsequent performance tests?

* * * * *

(b) You must conduct subsequent performance tests on all stacks associated with indurating furnaces to demonstrate continued compliance with the indurating furnace emission limits in tables 1 through 3 to this subpart according to the schedule developed by your permitting authority and shown in your title V permit, but no less frequent than twice per 5-year permit term. If a title V permit has not been issued, you must submit a testing plan and schedule, containing the information specified in paragraph (e) of this section, to the permitting authority for approval. For an indurating furnace with multiple stacks, the performance tests for all stacks must be conducted within 7 calendar days of commencement of the performance tests, to the extent practicable, and the indurating furnace and associated control device (where applicable) operating characteristics must remain representative and consistent for the duration of the stack tests. If you determine that the performance tests cannot be completed within 7 calendar days, the Administrator must be notified within 24 hours of making that determination. Performance testing for mercury is not required for furnaces using CEMS to demonstrate compliance with the mercury emission limits in table 2 to this subpart.

* * * * *

(e) * * *

(2) A schedule indicating when you will conduct subsequent performance tests for particulate matter, mercury, hydrogen chloride and hydrogen fluoride for each of the emission units.

■ 12. Section 63.9631 is amended by:

■ a. Revising and republishing paragraphs (d) through (f); and

■ b. Adding paragraphs (g) through (k).

The revisions and additions read as follows:

§ 63.9631 What are my monitoring requirements?

* * * * *

(d) For each dry ESP subject to the operating limits in § 63.9590(b)(3), you must follow the monitoring requirements in paragraph (d)(1) or (2) of this section.

(1) If the operating limit you choose to monitor is the 6-minute average opacity of emissions in accordance with § 63.9590(b)(3)(i), you must install, operate, and maintain a COMS according to the requirements in § 63.9632(f) and monitor the 6-minute average opacity of emissions exiting each control device stack according to the requirements in § 63.9633.

(2) If the operating limit you choose to monitor is average secondary voltage and average secondary current for each dry ESP field in accordance with § 63.9590(b)(3)(ii), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(b) through (e) and monitor the daily average secondary voltage and daily average secondary current according to the requirements in § 63.9633.

(e) For each wet ESP subject to the operating limits in § 63.9590(b)(4), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(b) through (e) and monitor the daily average secondary voltage, daily average stack outlet temperature, and daily average water flow rate according to the requirements in § 63.9633.

(f) For each wet scrubber and wet ESP subject to the operating limits in § 63.9590(b)(5), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(g) and monitor the daily average scrubber water flow rate and pH of the scrubber water effluent.

(g) For each ACI system subject to the operating limits in § 63.9590(b)(6), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(h) and (i) and monitor the daily average activated carbon injection rate and carrier gas flow rate.

(h) For each DSI system subject to the operating limits in § 63.9590(b)(7), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(h) and (i) and monitor the daily average sorbent injection rate and carrier gas flow rate.

(i) If you use any air pollution control device other than a baghouse, wet scrubber, dry ESP, wet ESP, DSI, or ACI, you must submit a site-specific monitoring plan that includes the information in paragraphs (i)(1) through (4) of this section. The monitoring plan is subject to approval by the Administrator. You must maintain a current copy of the monitoring plan onsite, and it must be available for inspection upon request. You must keep the plan for the life of the affected source or until the affected source is no longer subject to the requirements of this subpart.

(1) A description of the device.

(2) Test results collected in accordance with § 63.9621 verifying the performance of the device for reducing emissions of particulate matter, mercury, hydrogen chloride, and hydrogen fluoride to the atmosphere to the levels required by this subpart.

(3) A copy of the operation and maintenance plan required in § 63.9600(b).

(4) Appropriate operating parameters that will be monitored to maintain continuous compliance with the applicable emission limitation(s).

(j) If you elect to comply with the mercury limit in table 2 to this subpart using emissions averaging in accordance with an implementation plan approved under the provisions in § 63.9623(d) or you elect to adjust the activated carbon injection rate based on the taconite pellet production rate in accordance with the procedures in § 63.9634(n), you must determine and record the mass of taconite pellets produced each month by each furnace included in the emissions averaging group. The weight of taconite pellets produced must be determined by measurement using weigh hoppers, belt weigh feeders, or weighed quantities in shipments, or calculated using the bulk density and volume measurements.

(k) If you elect to demonstrate compliance with the mercury emissions limits in table 2 to this subpart using a CEMS to measure mercury emissions, you must comply with the requirements in (k)(1) through (5).

(1) Notify the Administrator one month before starting use of the CEMS and notify the Administrator 180-days before ceasing use of the CEMS.

(2) Each CEMS must be installed, certified, calibrated, and maintained according to the requirements of performance specifications 6 and 12A of 40 CFR part 60, appendix B, and quality assurance procedure 6 of 40 CFR part 60, appendix F.

(3) Operate the mercury CEMS in accordance with performance specification 12A of 40 CFR part 60, appendix B. The duration of the performance test must be 30 operating days. For each day in which the unit operates, you must obtain hourly mercury concentration data, and stack gas volumetric flow rate data.

(4) You must complete the initial performance evaluation of the CEMS within 180 days after notifying the Administrator and before starting to use the CEMS data in lieu of performance testing and monitoring operating parameters to demonstrate compliance.

(5) Collect CEMS hourly averages for all operating hours on a 30-day rolling average basis. The one-hour arithmetic averages, expressed in units of lb/LT, must be used to calculate 30-day rolling average emissions to determine compliance with the applicable emission limit in table 2 to this subpart.

■ 13. Section 63.9632 is amended by:

■ a. Revising paragraphs (f) introductory text and (f)(2); and

■ b. Adding paragraphs (g) through (i).

The revisions and additions read as follows:

§ 63.9632 What are the installation, operation, and maintenance requirements for my monitoring equipment?

* * * * *

(f) For each dry ESP subject to the opacity operating limit in § 63.9590(b)(3)(i), you must install, operate, and maintain each COMS according to the requirements in paragraphs (f)(1) through (4) of this section.

* * * * *

(2) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, you must develop and implement a quality control program for operating and maintaining each COMS according to § 63.8. At a minimum, the quality control program must include a daily calibration drift assessment, quarterly performance audit, and annual zero alignment of each COMS. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, you must develop and implement a quality control program for operating and maintaining each COMS according to § 63.8(a) and (b), (c)(1)(ii), (c)(2) through (8), (d)(1) and (2), and (e) through (g) and Procedure 3 in appendix F to 40 CFR part 60. At a minimum, the quality control program must include a daily calibration drift assessment, quarterly performance audit, and annual zero alignment of each COMS.

* * * * *

(g) For each pH measurement device, in addition to the requirements in paragraphs (b) through (e) of this section, you must meet the requirements in paragraphs (g)(1) through (4) of this section.

(1) The minimum accuracy of the pH measurement device must be ±0.2 pH units.

(2) Locate the pH sensor in a position that provides a representative measurement of scrubber effluent pH.

(3) Ensure the sample is properly mixed and representative of the fluid to be measured.

(4) Check the pH meter's calibration on at least two points every 8 hours of process operation.

(h) For each mass flow rate monitor used for measuring the sorbent or activated carbon injection rate, in addition to the requirements in paragraphs (b) through (e) of this section, you must meet the requirements of (h)(1) through (4) of this section.

(1) The minimum accuracy of the mass flow rate monitor must be ±5 percent over the normal range of flow measured.

(2) Locate the device in a position(s) that provides a representative measurement of the total sorbent injection rate.

(3) Install and calibrate the device in accordance with manufacturer's procedures and specifications.

(4) At least annually, conduct a performance evaluation of the injection rate monitoring system in accordance with your monitoring plan.

(i) For each carrier gas flow rate monitor, in addition to the requirements in paragraphs (b) through (e) of this section, you must meet the requirements of (i)(1) through (4) of this section.

(1) The minimum accuracy of the gas flow rate monitor must be ±5 percent over the normal range of flow measured or 280 liters per minute (10 cubic feet per minute), whichever is greater.

(2) Locate the device in a position(s) that provides a representative measurement of the carrier gas flow rate.

(3) Install and calibrate the device in accordance with manufacturer's procedures and specifications.

(4) At least annually, conduct a performance evaluation of the carrier gas flow rate monitoring system in accordance with your monitoring plan.

■ 14. Section 63.9634 is amended by revising paragraphs (a), (e)(4), (f)(4), (g) through (j) and adding paragraphs (k) through (n) to read as follows:

§ 63.9634 How do I demonstrate continuous compliance with the emission limitations that apply to me?

(a) For each affected source subject to an emission limit in table 1 to this subpart, you must demonstrate continuous compliance by meeting the requirements in paragraphs (b) through (h) of this section.

* * * * *

(e) * * *

(4) If the daily average pressure drop or daily average scrubber water flow rate is below the operating limits established for a corresponding emission unit or group of similar emission units, you must then follow the corrective action procedures in paragraph (l) of this section.

(f) * * *

(4) On or before January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, if the daily average scrubber water flow rate, daily average fan amperage, or daily average pressure drop is below the operating limits established for a corresponding emission unit or group of similar emission units, you must then follow the corrective action procedures in paragraph (l) of this section. After January 28, 2022, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, if the daily average scrubber water flow rate or daily average fan amperage, is below the operating limits established for a corresponding emission unit or group of similar emission units, you must then follow the corrective action procedures in paragraph (l) of this section.

(g) For each dry ESP subject to operating limits in § 63.9590(b)(3), you

must demonstrate continuous compliance by completing the requirements of paragraph (g)(1) or (2) of this section.

(1) If the operating limit for your dry ESP is a 6-minute average opacity of emissions value, then you must follow the requirements in paragraphs (g)(1)(i) through (iii) of this section.

(i) Maintaining the 6-minute average opacity of emissions at or below the maximum level established during the initial or subsequent performance test.

(ii) Operating and maintaining each COMS and reducing the COMS data according to § 63.9632(f).

(iii) If the 6-minute average opacity of emissions is above the operating limits established for a corresponding emission unit, you must then follow the corrective action procedures in paragraph (l) of this section.

(2) If the operating limit for your dry ESP is the daily average secondary voltage and daily average secondary current for each field, then you must follow the requirements in paragraphs (g)(2)(i) through (iv) of this section.

(i) Maintaining the daily average secondary voltage or daily average secondary current for each field at or above the minimum levels established during the initial or subsequent performance test.

(ii) Operating and maintaining each dry ESP CPMS according to § 63.9632(b) and recording all information needed to document conformance with these requirements.

(iii) Collecting and reducing monitoring data for secondary voltage or secondary current for each field according to § 63.9632(c) and recording all information needed to document conformance with these requirements.

(iv) If the daily average secondary voltage or daily average secondary current for each field is below the operating limits established for a corresponding emission unit, you must then follow the corrective action procedures in paragraph (l) of this section.

(h) For each wet ESP subject to the operating limits for secondary voltage, stack outlet temperature, and water flow rate in § 63.9590(b)(4), you must demonstrate continuous compliance by completing the requirements of paragraphs (h)(1) through (4) of this section.

(1) Maintaining the daily average secondary voltage and daily average scrubber water flow rate for each field at or above the minimum levels established during the initial or subsequent performance test. Maintaining the daily average stack outlet temperature at or below the maximum levels established during the initial or subsequent performance test.

(2) Operating and maintaining each wet ESP CPMS according to § 63.9632(b) and recording all information needed to document conformance with these requirements.

(3) Collecting and reducing monitoring data for secondary voltage, stack outlet temperature, and water flow rate according to § 63.9632(c) and recording all information needed to document conformance with these requirements.

(4) If the daily average secondary voltage, stack outlet temperature, or water flow rate does not meet the operating limits established for a corresponding emission unit, you must then follow the corrective action procedures in paragraph (l) of this section.

(i) For each affected indurating furnace subject to a hydrogen chloride and hydrogen fluoride emission limit in table 3 to this subpart, you must demonstrate continuous compliance by meeting the requirements in paragraphs (i)(1) and (2) of this section.

(1) For each wet scrubber and wet ESP subject to the operating limits for scrubber water flow rate and pH in § 63.9590(b)(5), you must demonstrate continuous compliance by completing the requirements of paragraphs (i)(1)(i) through (iv) of this section.

(i) Maintaining the daily average scrubber water flow rate and daily average pH of the scrubber water effluent at or above the minimum level established during the most recent performance test. If a higher average flow rate is measured during the last PM performance test, the operating limit for daily average scrubber water flow rate is the highest average scrubber water flow rate measured during the last PM performance test.

(ii) Operating and maintaining each of the CPMS used to measure scrubber water flow rate and pH according to § 63.9632(g) and recording all information needed to document conformance with these requirements.

(iii) Collecting and reducing monitoring data for scrubber water flow rate and pH according to § 63.9632(c) and recording all information needed to document conformance with these requirements.

(iv) If the daily average scrubber water flow rate or daily average pH is below the operating limits established for control device, you must follow the corrective action procedures in paragraph (l) of this section.

(2) For each DSI subject to the operating limits for sorbent injection rate and carrier gas flow rate in § 63.9590(b)(7), you must demonstrate continuous compliance by completing the requirements of paragraphs (i)(2)(i) through (iv) of this section.

(i) Maintain the daily average sorbent injection rate and carrier gas flow rate at or above the minimum level established during the most recent performance test.

(ii) Operate and maintain each CPMS used to measure the sorbent injection rate according to § 63.9632(h) and the carrier gas flow rate according to § 63.9632(i) and recording all information needed to document compliance with these requirements.

(iii) Collect and reduce monitoring data for the sorbent injection rate and carrier gas flow rate according to § 63.9632(c) and recording all information needed to document compliance with these requirements.

(iv) If the daily average the sorbent injection rate or carrier gas flow rate is below the operating limit established for the control device, you must follow the corrective action procedures in paragraph (l) of this section.

(j) For each affected indurating furnace using ACI to comply with the mercury emission limit in table 2 to this subpart, you must demonstrate continuous compliance by meeting the requirements of paragraphs (j)(1) or (2) of this section.

(1) If you use CEMS to demonstrate compliance, you must comply with the requirements in paragraphs (j)(1)(i) and (ii) of this section.

(i) You must operate a mercury CEMS in accordance with performance specification 12A at 40 CFR part 60, appendix B; these monitoring systems must be quality assured according to procedure 5 of 40 CFR 60, appendix F. You must demonstrate compliance with the mercury emissions limit using a 30-day rolling average of these 1-hour mercury concentrations or mass emissions rates, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part.

(ii) Owners or operators using a mercury CEMS to determine mass emission rate must install, operate, calibrate and maintain an instrument for continuously measuring and recording the mercury mass emissions rate to the atmosphere according to the requirements of performance specification 6 at 40 CFR part 60, appendix B and conducting an annual relative accuracy test of the continuous emission rate monitoring system according to section 8.2 of performance specification 6.

(2) If you do not use CEMS to demonstrate compliance, you must demonstrate continuous compliance by meeting the requirements of paragraphs (j)(2)(i) through (iv) of this section.

(i) Maintain the daily average activated carbon injection rate and carrier gas flow rate at or above the minimum level established during the most recent performance test.

(ii) Operate and maintain each CPMS used to measure the activated carbon injection rate according to § 63.9632(h) and the carrier gas flow rate according to § 63.9632(i), and record all information needed to document compliance with these requirements.

(iii) Collect and reduce monitoring data for the activated carbon injection rate and carrier gas flow rate according to § 63.9632(c) and record all information needed to document conformance with these requirements.

(iv) If the daily average of the activated carbon injection rate or carrier gas flow rate is below the operating limit established for the control device, you must follow the corrective action procedures in paragraph (l) of this section.

(k) If you use an air pollution control device other than a wet scrubber, dynamic wet scrubber, dry ESP, wet ESP, DSI, ACI, or baghouse, you must submit a site-specific monitoring plan in accordance with § 63.9631(f). The site-specific monitoring plan must include the site-specific procedures for demonstrating initial and continuous compliance with the corresponding operating limits.

(l) If the daily average operating parameter value for an emission unit or group of similar emission units does not meet the corresponding established operating limit, you must then follow the procedures in paragraphs (l)(1) through (4) of this section.

(1) You must initiate and complete initial corrective action within 10 calendar days and demonstrate that the initial corrective action was successful. During any period of corrective action, you must continue to monitor, and record all required operating parameters for equipment that remains in operation. After the initial corrective action, if the daily average operating parameter value for the emission unit or group of similar emission units meets the operating limit established for the corresponding unit or group, then the corrective action was successful and the emission unit or group of similar emission units is in compliance with the established operating limits.

(2) If the initial corrective action required in paragraph (l)(1) of this section was not successful, then you must complete additional corrective action within 10 calendar days and demonstrate that the subsequent corrective action was successful. During any period of corrective action, you must continue to monitor, and record all required operating parameters for equipment that remains in operation. If the daily average operating parameter value for the emission unit or group of similar emission units meets the operating limit established for the corresponding unit or group, then the corrective action was successful, and the emission unit or group of similar emission units is in compliance with the established operating limits.

(3) If the second attempt at corrective action required in paragraph (l)(2) of this section was not successful, then you must repeat the procedures of paragraph (l)(2) of this section until the corrective action is successful. If the third attempt at corrective action is unsuccessful, you must conduct another performance test in accordance with the procedures in § 63.9622(f) and report to the Administrator as a deviation the third unsuccessful attempt at corrective action.

(4) After the third unsuccessful attempt at corrective action, you must submit to the Administrator the written report required in paragraph (l)(3) of this section within 5 calendar days after the third unsuccessful attempt at corrective action. This report must notify the Administrator that a deviation has occurred and document the types of corrective measures taken to address the problem that resulted in the deviation of established operating parameters and the resulting operating limits.

(m) If you elect to comply with the mercury limit in table 2 to this subpart using emissions averaging in accordance with an implementation plan approved under the provisions in § 63.9623(d), you must comply with the requirements in paragraphs (m)(1) through (5) of this section.

(1) For furnaces included in the emissions averaging group that do not use mercury CEMS, you must comply with the requirements in paragraph (m)(1)(i) or (ii) as applicable.

(i) For furnaces equipped with ACI systems, you must comply with the requirements in paragraph (j) of this section.

(ii) For furnaces equipped with a mercury control device or method other than ACI, you must comply with your site-specific monitoring plan in accordance with the requirements in paragraph (k) of this section.

(2) For furnaces included in the emissions averaging group that use mercury CEMS, you must comply with the requirements in paragraph (i)(1) of this section.

(3) Calculate the monthly production-weighted average emission rate using either the mercury CEMS data or mercury emission rate determined during the last performance test and the actual taconite pellet production data for each furnace included in the emissions averaging option, as shown in Equation 6 of this section.

$$E_g = \frac{\sum_{f=1}^{n}(E_f \times P_f)}{\sum_{f=1}^{n} P_f} \quad (Eq. 6)$$

Where:

E_g = Monthly production-weighted average mercury emission rate for month ''g'' for the group of indurating furnaces, lb/LT of pellets produced,

E_f = Average mercury emission rate for furnace ''f'', as determined using either mercury CEMS data or the emission rate determined during the last compliance stack test and calculated using Equation 5 of § 63.9621(d)(7)(i), lb/LT of pellets produced,

P_f = Total monthly production of finished taconite pellets for furnace ''f'', in LT, and

n = Number of furnaces in the averaging group.

(4) Until 12 monthly weighted average emission rates have been accumulated, the monthly weighted average emissions rate, calculated as shown in paragraph (m)(3) of this section, must not exceed the mercury emission limit in table 3 of this subpart in any calendar month.

(5) After 12 monthly weighted average emission rates have been accumulated, for each subsequent calendar month, you must use Equation 7 of this section to calculate the 12-month rolling average of the monthly weighted average emission rates for the current month and the previous 11 months. The 12-month rolling weighted average emissions rate for the furnaces included in the group must not exceed the mercury emission limit in table 3 of this subpart.

$$E_{avg} = \frac{\sum_{i=1}^{12} E_i}{12} \quad Eq. 7$$

Where:

E_{avg} = 12-month rolling average emission rate, lb/LT.

E_i = Monthly weighted average for month ''i'' calculated as shown in Equation 6 of this section.

(n) You may elect to demonstrate continuous compliance with the mercury limit in table 2 to this subpart by adjusting the activated carbon injection rate based on the taconite pellet production rate. You must comply with the requirements in

paragraphs (n)(1) through (7) of this section.

(1) Measure the activated carbon injection and mercury emissions rate at a minimum of three different production levels corresponding to the maximum, minimum and median finished taconite pellet production rates, using the methods specified in § 63.9620(k).

(2) Develop a correlation curve by plotting the production rate and corresponding carbon injection rate for the maximum, median and minimum production rates. Use only data where the mercury emission rate is below the applicable mercury emissions standard in table 2 to this subpart. Plot the production rates as the independent (or x) variable and the activated carbon injection rate as the dependent (or y) variable for each pellet production rate. Construct the graph by drawing straight line segments between each point plotted.

(3) You must develop and submit to the applicable regulatory authority for review and approval, an implementation plan no later than 180 days before the date you intend to demonstrate compliance by adjusting the activated carbon injection rate based on the taconite pellet production. You must include the information listed in paragraphs (n)(3)(i) through (iv) of this section in your implementation plan.

(i) Identification of the indurating furnace, including the typical maximum and minimum taconite pellet production rate, mercury control technology installed, and types of fuel(s) that will be burned.

(ii) The mercury emissions and activated carbon injection rates at maximum, median and minimum taconite pellet production rates, and the methods used to measure the mercury emissions, activated carbon injection rate and taconite pellet production.

(iii) The correlation curve developed in paragraph (n)(2) of this section.

(iv) The date on which you are requesting to commence adjusting the activated carbon rate based on the taconite production rate.

(4) Install, calibrate, maintain, and operate a CPMS to monitor and record the activated carbon injection rate and taconite pellet production rate.

(5) Maintain the carbon injection rate at or above the rate established by the correlation curve corresponding to the taconite pellet production rate. If the taconite pellet production rate drops below the minimum rate established in paragraph (n)(3) of this section, you must maintain the activated carbon injection rate at or above the rate established for the minimum taconite pellet production rate.

(6) Keep records of the activated carbon injection rate and taconite pellet production rate for each hour of operation in order to demonstrate that the activated carbon injection rate remains in compliance with paragraph (n)(5) of this section.

(7) Establish a new correlation curve at least twice per 5-year permit term.

■ 15. Section 63.9636 is amended by revising paragraph (a) introductory text to read as follows:

§ 63.9636 How do I demonstrate continuous compliance with the operation and maintenance requirements that apply to me?

(a) For each control device used to comply with an emission standard in § 63.9590(a), you must demonstrate continuous compliance with the operation and maintenance requirements in § 63.9600(b) by completing the requirements of paragraphs (a)(1) through (4) of this section.

* * * * *

■ 16. Section 63.9637 is amended by revising paragraph (a) to read as follows:

§ 63.9637 What other requirements must I meet to demonstrate continuous compliance?

(a) *Deviations.* You must report each instance in which you did not meet each emission limitation in tables 1 through 3 to this subpart that applies to you. You also must report each instance in which you did not meet the work practice standards in § 63.9591 and each instance in which you did not meet each operation and maintenance requirement in § 63.9600 that applies to you. These instances are deviations from the emission limitations, work practice standards, and operation and maintenance requirements in this subpart. These deviations must be reported in accordance with the requirements in § 63.9641.

* * * * *

■ 17. Section 63.9640 is amended by adding paragraphs (f) and (g) to read as follows:

§ 63.9640 What notifications must I submit and when?

* * * * *

(f) If you elect to use CEMS to demonstrate compliance with the mercury standards in table 2 to this subpart, you must submit a notification of intent to use CEMS at least one month prior to making the change. If you are currently using CEMS to demonstrate compliance with the mercury standards, you must submit a notification of intent to cease using CEMS to demonstrate compliance at least 180 days prior to making the change.

(g) If you elect to use the mercury emissions averaging compliance option, you must submit a notification of intent at least 180 days prior to making the change. If you are currently using the mercury emissions averaging compliance option, you must submit a notification of intent to cease using emissions averaging at least 30 days prior to making the change.

■ 18. Section 63.9641 is amended by:

■ a. Revising paragraph (b)(6);

■ b. Revising and republishing paragraph (b)(8);

■ c. Revising paragraphs (c), (e) and (f)(3); and

■ d. Adding paragraph (i).

The revisions and additions read as follows:

§ 63.9641 What reports must I submit and when?

* * * * *

(b) * * *

(6) If there were no periods during which a continuous monitoring system (including a CPMS, COMS, or CEMS) was out-of-control as specified in § 63.8(c)(7), then provide a statement that there were no periods during which a continuous monitoring system was out-of-control during the reporting period.

* * * * *

(8) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, for each deviation from an emission limitation occurring at an affected source where you are using a continuous monitoring system (including a CPMS or COMS) to comply with the emission limitation in this subpart, you must include the information in paragraphs (b)(1) through (4) of this section and the information in paragraphs (b)(8)(i) through (xi) of this section. This includes periods of startup, shutdown, and malfunction. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, for each deviation from an emission limitation occurring at an affected source where you are using a continuous monitoring system (including a CPMS, COMS, or CEMS) to comply with the emission limitation in this subpart, you must include the information in paragraphs (b)(1) through

(4) of this section and the information in paragraphs (b)(8)(i) through (xi) of this section.

(i) The date and time that each malfunction started and stopped.

(ii) The start date, start time, and duration in hours (or minutes for COMS) that each continuous monitoring system was inoperative, except for zero (low-level) and high-level checks.

(iii) The start date, start time, and duration that each continuous monitoring system was out-of-control, including the information in § 63.8(c)(8).

(iv) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, for each affected source or equipment, the date and time that each deviation started and stopped, the cause of the deviation, and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, for each affected source or equipment, the date and time that each deviation started and stopped, the cause of the deviation, and whether each deviation occurred during a period of malfunction or during another period

(v) The total duration of all deviations for each Continuous Monitoring System (CMS) during the reporting period, the total operating time in hours of the affected source during the reporting period, and the total duration as a percent of the total source operating time during that reporting period.

(vi) On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, a breakdown of the total duration of the deviations during the reporting period including those that are due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes. After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, a breakdown of the total duration of the deviations during the reporting period including those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

(vii) The total duration of continuous monitoring system downtime for each continuous monitoring system during the reporting period, the total operating time in hours of the affected source during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total source operating time during the reporting period.

(viii) A brief description of the process units.

(ix) The monitoring equipment manufacturer and model number and the pollutant or parameter monitored.

(x) The date of the latest continuous monitoring system certification or audit.

(xi) A description of any changes in continuous monitoring systems, processes, or controls since the last reporting period.

(c) *Submitting compliance reports electronically.* Beginning on January 25, 2021, submit all subsequent compliance reports to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed to be CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if persons wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Submit the file following the procedures in paragraph (c)(1) or (2) of this section. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph (c). All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c) emissions data is not entitled to confidential treatment, and EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. On or before January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your startup, shutdown, and malfunction plan you must submit an immediate startup, shutdown and malfunction report according to the requirements in § 63.10(d)(5)(ii). After January 25, 2021, for affected sources that commenced construction or reconstruction on or before September 25, 2019, and after July 28, 2020, or upon start-up, which ever date is later, for affected sources that commenced construction or reconstruction after September 25, 2019, an immediate startup, shutdown, and malfunction report is not required.

(1) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings and be flagged to the attention of the Taconite Iron Ore Processing Sector Lead. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(2) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: U.S. EPA, Attn: OAQPS Document Control Officer and Taconite Iron Ore Processing Sector Lead, Mail Drop: C404–02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, NC 27711. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

* * * * *

(e) *Immediate corrective action report.* If you had three unsuccessful attempts of applying corrective action as described in § 63.9634(l) on an emission unit or group of emission units, then you must submit an immediate corrective action report. Within 5 calendar days after the third unsuccessful attempt at corrective action, you must submit to the Administrator a written report in

accordance with § 63.9634(l)(3) and (4). This report must notify the Administrator that a deviation has occurred and document the types of corrective measures taken to address the problem that resulted in the deviation of established operating parameters and the resulting operating limits.

(f) * * *

(3) *Confidential business information (CBI).*

(i) The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (f)(1) or (2) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA.

(ii) The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website.

(iii) Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

(iv) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings and be flagged to the attention of the Group Leader, Measurement Policy Group. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(v) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: U.S. EPA, Attn: OAQPS Document Control Officer and Measurement Policy Group Lead, Mail Drop: C404–02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, NC 27711. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

(vi) All CBI claims must be asserted at the time of submission. Anything submitted using CEDRI cannot later be claimed CBI. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(vii) You must submit the same file submitted to the CBI office with the CBI omitted to the EPA via the EPA's CDX as described in § 63.9(k).

* * * * *

(i) *Use of CEMS for mercury.* If you use CEMS to demonstrate compliance with the mercury emissions limits in table 2 to this subpart, you must submit the results of the performance evaluation following the procedure specified in either paragraph (i)(1) or (2) of this section within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2).

(1) For performance evaluations of continuous monitoring systems measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT website. If you claim that some of the performance evaluation information being transmitted is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this section.

(2) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the ERT website at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 63.13.

■ 19. Section 63.9642 is amended by:

■ a. Revising paragraph (b) introductory text; and

■ b. Adding paragraphs (b)(5), (d), (e) and (f).

The revisions and additions read as follows:

§ 63.9642 What records must I keep?

* * * * *

(b) For each COMS and CEMS, you must keep the records specified in paragraphs (b)(1) through (5) of this section.

* * * * *

(5) If you use mercury CEMS to demonstrate compliance with the mercury emission standard in table 2 of the subpart in accordance with § 63.9623(e), records of requests for alternatives to the relative accuracy test for CEMS as required in § 63.8(f)(6)(i).

* * * * *

(d) If you elect the mercury emissions averaging compliance alternative pursuant to § 63.9623(d), you must keep a copy of the emission averaging implementation plan required in § 63.9623(d)(2), records of the taconite pellet production rate for each furnace included in the averaging, and all calculations required under § 63.9634(m).

(e) If you elect to adjust the activated carbon injection rate based on the taconite pellet production rate in accordance with the provisions in § 63.9634(n), you must keep a copy of the activated carbon injection implementation plan and records of the taconite pellet production rate and activated carbon injection rate.

(f) If you use CEMS to demonstrate compliance with the mercury emissions limits in table 2 to this subpart, you must keep records of the notifications required in § 63.9642(f).

■ 20. Section 63.9650 is revised to read as follows:

§ 63.9650 What parts of the General Provisions apply to me?

Table 4 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.16 apply to you.

■ 21. Section 63.9652 is amended by adding definitions in alphabetical order for ''Activated carbon injection (ACI) system'', ''Dry sorbent injection (DSI) system'', and ''Electrostatic precipitator (ESP)'' to read as follows:

§ 63.9652 What definitions apply to this subpart?

* * * * *

Activated carbon injection (ACI) system means an add-on air pollution control system in which activated carbon or brominated activated carbon is injected into the flue gas steam

upstream of a particulate matter control device to adsorb mercury in the exhaust stream. The absorbed mercury remains absorbed to the activated carbon and is collected in a primary or secondary particulate matter control device.

* * * * *

Dry sorbent injection (DSI) system means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gas in the exhaust stream forming a dry powder material that is collected by a primary or secondary particulate matter control device.

* * * * *

Electrostatic Precipitator (ESP) means a device that removes suspended particulate matter from flue exhaust by applying a high-voltage electrostatic charge to the particles, which are then attracted to and collected on a grounded plate. In a dry ESP, the particles are dislodged from the plate by rapping and are collected in a hopper positioned below the plate. In a wet ESP, particulates are removed from the plate by washing with water.

* * * * *

■ 22. Revise the table heading and introductory paragraph for table 1 to subpart RRRRR of part 63 to read as follows:

Table 1 to Subpart RRRRR of Part 63—Particulate Matter Emission Limits

As required in § 63.9590(a), you must comply with each applicable particulate matter emission limit in the following table:

* * * * *

■ 22. Table 2 to subpart RRRRR is redesignated as table 4 to subpart RRRRR.

■ 23. Add a new table 2 to subpart RRRRR to read as follows:

TABLE 2 TO SUBPART RRRRR OF PART 63—MERCURY EMISSION LIMITS FOR INDURATING FURNACES

[As required in § 63.9590(a), you must comply with each applicable mercury emission limit in the following table:]

For . . .	You must meet the following emission limits . . .
1. Indurating furnaces constructed or reconstructed before May 15, 2023.	Either: (1) Mercury emissions from each furnace must not exceed 1.4×10^{-5} lb/LT of taconite pellets produced, or (2) Production-weighted average mercury emissions for a group of indurating furnaces, calculated according to Equation 6 in § 63.9634(m)(3), must not exceed 1.3×10^{-5} lb/LT.
2. Indurating furnaces constructed or reconstructed on or after May 15, 2023.	Mercury emissions from each furnace must not exceed 2.6×10^{-6} lb/LT.

■ 24. Add Table 3 to Subpart RRRRR to read as follows:

TABLE 3 TO SUBPART RRRRR OF PART 63—HYDROGEN CHLORIDE AND HYDROGEN FLUORIDE EMISSION LIMITS FOR INDURATING FURNACES

[As required in § 63.9590(a), you must comply with each applicable hydrogen chloride and hydrogen fluoride emission limit in the following table:]

For . . .	You must meet the following emission limits . . .
1. Indurating furnaces constructed or reconstructed before May 15, 2023.	Hydrogen chloride emissions must not exceed 4.6×10^{-2} lb/Long Ton of taconite pellets produced. Hydrogen fluoride emissions must not exceed 1.2×10^{-2} lb/Long Ton of taconite pellets produced.
2. Indurating furnaces constructed or reconstructed on or after May 15, 2023.	Hydrogen chloride emissions must not exceed 4.4×10^{-4} lb/Long Ton of taconite pellets produced Hydrogen fluoride emissions must not exceed 3.3×10^{-4} lb/Long Ton of taconite pellets produced.

■ 25. Revise newly redesignated table 4 to subpart RRRRR to read as follows:

TABLE 4 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63

[As required in § 63.9650, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.1(a)(1)–(4)	Applicability	Yes.	
§ 63.1(a)(5)	[Reserved]	No.	
§ 63.1(a)(6)	Applicability	Yes.	
§ 63.1(a)(7)–(9)	[Reserved]	No.	
§ 63.1(a)(10)–(14)	Applicability	Yes.	
§ 63.1(b)(1)	Initial Applicability Determination	Yes.	
§ 63.1(b)(2)	[Reserved]	No.	
§ 63.1(b)(3)	Initial Applicability Determination	Yes.	
§ 63.1(c)(1)–(2)	Applicability After Standard Established, Permit Requirements.	Yes.	

TABLE 4 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63—Continued

[As required in § 63.9650, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.1(c)(3)–(4)	[Reserved]	No.	
§ 63.1(c)(5)	Area Source Becomes Major	Yes.	
§ 63.1(c)(6)	Reclassification	Yes.	
§ 63.1(d)	[Reserved]	No.	
§ 63.1(e)	Equivalency of Permit Limits	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(2)	Prohibited Activities	Yes.	
§ 63.4(a)(3)–(5)	[Reserved]	No.	
§ 63.4(b)–(c)	Circumvention, Fragmentation	Yes.	
§ 63.5(a)(1)–(2)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(1)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(2)	[Reserved]	No.	
§ 63.5(b)(3)–(4)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(5)	[Reserved]	No.	
§ 63.5(b)(6)	Applicability	Yes.	
§ 63.5(c)	[Reserved]	No.	
§ 63.5(d)(1)–(4)	Application for Approval of Construction or Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction or Reconstruction.	Yes.	
§ 63.5(f)	Approval Based on State Review	Yes.	
§ 63.6(a)	Compliance with Standards and Maintenance Requirements.	Yes.	
§ 63.6(b)(1)–(5)	Compliance Dates for New/Reconstructed Sources.	Yes.	
§ 63.6(b)(6)	[Reserved]	No.	
§ 63.6(b)(7)	Compliance Dates for New/Reconstructed Sources.	Yes.	
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources.	Yes.	
§ 63.6(c)(3)–(4)	[Reserved]	No.	
§ 63.6(c)(5)	Compliance Dates for Existing Sources.	Yes.	
§ 63.6(d)	[Reserved]	No.	
§ 63.6(e)(1)(i)	Operation and Maintenance Requirements—General Duty to Minimize Emissions.	Yes, on or before the compliance date specified in § 63.9600(a). No, after the compliance date specified in § 63.9600(a).	See § 63.9600(a) for general duty requirement.
§ 63.6(e)(1)(ii)	Operation and Maintenance Requirements—Requirement to Correct Malfunction as Soon as Possible.	No.	
§ 63.6(e)(1)(iii)	Operation and Maintenance Requirements—Enforceability.	Yes.	
§ 63.6(e)(2)	[Reserved]	No.	
§ 63.6(e)(3)	Startup, Shutdown, Malfunction (SSM) Plan.	Yes, on or before the compliance date specified in § 63.9610(c). No, after the compliance date specified in § 63.9610(c).	
§ 63.6(f)(1)	SSM exemption	No	See § 63.9600(a).
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
§ 63.6(g)(1)–(3)	Alternative Nonopacity Standard	Yes.	
§ 63.6(h), except (h)(1).	Compliance with Opacity and Visible Emission (VE) Standards.	No	Opacity limits in subpart RRRRR are established as part of performance testing in order to set operating limits for ESPs.
§ 63.6(h)(1)	Compliance except during SSM	No	See § 63.9600(a).
§ 63.6(i)(1)–(14)	Extension of Compliance	Yes.	
§ 63.6(i)(15)	[Reserved]	No.	
§ 63.6(i)(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Presidential Compliance Exemption	Yes.	
§ 63.7(a)(1)–(2)	Applicability and Performance Test Dates.	No	Subpart RRRRR specifies performance test applicability and dates.
§ 63.7(a)(3)–(4)	Performance Testing Requirements	Yes.	
§ 63.7(b)	Notification	Yes.	
§ 63.7(c)	Quality Assurance/Test Plan	Yes.	

TABLE 4 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63—Continued

[As required in § 63.9650, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.7(d)	Testing Facilities	Yes.	
§ 63.7(e)(1)	Conduct of Performance Tests	No	See § 63.9621.
§ 63.7(e)(2)–(4)	Conduct of Performance Tests	Yes.	
§ 63.7(f)	Alternative Test Method	Yes.	
§ 63.7(g)	Data Analysis	Yes	Except this subpart specifies how and when the performance test results are reported.
§ 63.7(h)	Waiver of Tests	Yes.	
§ 63.8(a)(1)–(2)	Monitoring Requirements	Yes.	
§ 63.8(a)(3)	[Reserved]	No.	
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart RRRRR does not require flares.
§ 63.8(b)(1)–(3)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)(i)	Operation and Maintenance of CMS	Yes, on or before the compliance date specified in § 63.9632(b)(4). No, after the compliance date specified in § 63.9632(b)(4).	See § 63.9632 for operation and maintenance requirements for monitoring. See § 63.9600(a) for general duty requirement.
§ 63.8(c)(1)(ii)	Spare parts for CMS Equipment	Yes.	
§ 63.8(c)(1)(iii)	SSM Plan for CMS	Yes, on or before the compliance date specified in § 63.9632(b)(4). No, after the compliance date specified in § 63.9632(b)(4).	
§ 63.8(c)(2)–(3)	CMS Operation/Maintenance	Yes.	
§ 63.8(c)(4)	Frequency of Operation for CMS	No	Subpart RRRRR specifies requirements for operation of CMS.
§ 63.8(c)(5)–(8)	CMS Requirements	Yes	CMS requirements in § 63.8(c)(5) and (6) apply only to COMS for dry ESPs.
§ 63.8(d)(1)–(2)	Monitoring Quality Control	Yes.	
§ 63.8(d)(3)	Monitoring Quality Control	No	See § 63.9632(b)(5).
§ 63.8(e)	Performance Evaluation for CMS	Yes.	
§ 63.8(f)(1)–(5)	Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Relative Accuracy Test Alternative (RATA).	Yes	Only if using continuous emission monitoring systems to demonstrate compliance with Table 2 to this subpart.
§ 63.8(g)(1)–(g)(4)	Data Reduction	Yes.	
§ 63.8(g)(5)	Data That Cannot Be Used	No	Subpart RRRRR specifies data reduction requirements.
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in § 63.9(g) apply to COMS for dry ESPs.
§ 63.9(k)	Electronic reporting procedures	Yes	Only as specified in § 63.9(j)
§ 63.10(a)	Recordkeeping and Reporting, Applicability and General Information.	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements	Yes.	
§ 63.10(b)(2)(i)	Records of SSM	No	See § 63.9642 for recordkeeping when there is a deviation from a standard.
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	No	See § 63.9642 for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	
§ 63.10(b)(2)(iv)	Actions Taken to Minimize Emissions During SSM.	No.	
§ 63.10(b)(2)(v)	Actions Taken to Minimize Emissions During SSM.	No.	
§ 63.10(b)(2)(vi)	Recordkeeping for CMS Malfunctions	Yes.	
§ 63.10(b)(2)(vii)–(xii)	Recordkeeping for CMS	Yes.	
§ 63.10(b)(2)(xiii)	Records for Relative Accuracy Test	No.	
§ 63.10(b)(2)(xiv)	Records for Notification	Yes.	
§ 63.10(b)(3)	Applicability Determinations	Yes.	

TABLE 4 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63—Continued

[As required in § 63.9650, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)	Records of Excess Emissions and Parameter Monitoring Exceedances for CMS.		Subpart RRRRR specifies recordkeeping requirements.
§ 63.10(c)(9)	[Reserved]	No.	
§ 63.10(c)(10)–(14)	CMS Recordkeeping	Yes.	
§ 63.10(c)(15)	Use of SSM Plan	No.	
§ 63.10(d)(1)–(2)	General Reporting Requirements	Yes	Except this subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting opacity or VE observations	No	Subpart RRRRR does not have opacity and VE standards that require the use of EPA Method 9 of appendix A–4 to 40 CFR part 60 or EPA Method 22 of appendix A–7 to 40 CFR part 60.
§ 63.10(d)(5)	SSM Reports	Yes, on or before the compliance date specified in § 63.9641(b)(4). No, after the compliance date specified in § 63.9641(b)(4).	See § 63.9641 for malfunction reporting requirements.
§ 63.10(e)	Additional Reporting Requirements	Yes, except a breakdown of the total duration of excess emissions due to startup/shutdown in63.10(e)(3)(vi)(I) is not required and when the summary report is submitted through CEDRI, the report is not required to be titled ''Summary Report-Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance.''.	The electronic reporting template combines the information from the summary report and excess emission report with the Subpart RRRRR compliance report.
§ 63.10(f)	Waiver for Recordkeeping or Reporting.	Yes.	
§ 63.11	Control Device and Work Practice Requirements.	No	Subpart RRRRR does not require flares.
§ 63.12(a)–(c)	State Authority and Delegations	Yes.	
§ 63.13(a)–(c)	State/Regional Addresses	Yes.	
§ 63.14(a)–(t)	Incorporation by Reference	Yes.	
§ 63.15(a)–(b)	Availability of Information and Confidentiality.	Yes.	
§ 63.16	Performance Track Provisions	Yes.	

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