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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0452; Project Identifier MCAI–2021–01356–A; Amendment 39–22176; AD 2022–19–07]

RIN 2120–AA64

Airworthiness Directives; Piaggio Aviation S.p.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Piaggio Aviation S.p.A. (Piaggio) Model P–180 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as accumulation of water and subsequent freezing in the pitot-tube, which results in pitot-tube blockage. This AD requires modifying the total air temperature (TAT) probe heater electrical circuit and revising your existing airplane flight manual (AFM). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2022.

ADDRESSES: For service information identified in this final rule, contact Piaggio Aero Industries S.p.A, P180 Customer Support, Via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: (+39) 331 679 74 93; email: *technicalsupport@piaggioaerospace.it.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2022–0452.

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0452; 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 final rule, the MCAI, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Piaggio Model P–180 airplanes. The NPRM published in the **Federal Register** on April 11, 2022 (87 FR 21034). The NPRM was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2019–0144, dated June 19, 2019 (referred to after this as ''the MCAI''), to address an unsafe condition on all Piaggio Model P.180 Avanti and Avanti II airplanes. The MCAI states:

> Occurrences of pitot-tube blockage were reported, leading to in-flight air data loss. Investigation results indicated that accumulation of water and subsequent freezing was the failure cause.
>
> This condition, if not corrected, could lead to unreliable indication or loss of in-flight air data provided by systems deriving their data from measuring air pressure, possibly resulting in loss of control of the aeroplane.
>
> To address this potentially unsafe condition, Piaggio issued the applicable AFM TC [Piaggio Aviation P.180 AVANTI II/EVO Temporary Change 79, dated September 17, 2018; and Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019], providing instructions to switch on pitot-tube heater before taxi if operation in heavy rain, snow or icing condition is expected. To prevent concurrent activation of TAT probe heater on ground, which could lead to temporary air data indications failure, Piaggio issued the applicable SBs [Piaggio Aviation Service Bulletin No. 80–0430, Revision 1; and Piaggio Aero Industries Service Bulletin No. 80–0457, Original Issue], providing modification instructions to inhibit on-ground power supply to TAT probe heater, when the pitot-tube heater is activated.
>
> For the reasons described above, this [EASA] AD requires amendment of the applicable AFM and, for certain aeroplanes, modification of the TAT probe heater electrical circuit.

You may examine the MCAI in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0452.

In the NPRM, the FAA proposed to require modifying the TAT probe heater electrical circuit and revising your existing AFM. The FAA is issuing this AD to prevent blockage of the pitot-tube. The unsafe condition, if not addressed, could result in temporary air data indications failure, which could result in loss of control of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Piaggio. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Update Contact Information for Piaggio

Piaggio requested that the FAA revise the NPRM to update the contact information provided for Piaggio service information.

The FAA agrees and has updated the contact information for Piaggio throughout this final rule accordingly.

Request Regarding the Background Information

Piaggio requested the FAA remove the extra reference ''and No. 79'' from the quoted MCAI statement in the Background section that reads ''To address this potentially unsafe condition, Piaggio issued the applicable AFM TC [Piaggio Aviation P.180 AVANTI II/EVO Temporary Change 79, dated September 17, 2018; and Piaggio

Aviation P.180 AVANTI Temporary Change No. 36 and No. 79]. . . .''

The FAA agrees and has deleted ''and No. 79'' from the quoted MCAI statement in the Background section of this AD. Instead, that text has been replaced with the date of Piaggio Aviation P.180 AVANTI Temporary Change No. 36, which was originally intended to be provided. This change does not alter the intent of that language.

Request To Remove Specific Service Bulletin Revision Level

Piaggio requested that paragraphs (g)(2)(ii) and (g)(3)(iii) of the proposed AD be revised to remove the revision number and date from the service bulletin reference specified in those paragraphs. Piaggio explained that this change is necessary because the service bulletin, independently from the revision, introduces the new Magnaghi landing gear in lieu of the Safran landing gear.

The FAA partially agrees. The FAA concurs that the referenced service bulletin up to Revision 2 independent of the revision level introduces the new Magnaghi landing gear in lieu of the Safran landing gear. However, the FAA cannot remove the revision level because the FAA has no way of knowing the language and content of future revisions. The FAA has referenced the service bulletin as ''up to Revision 2'' in paragraphs (g)(2)(ii) and (g)(3)(iii) of this AD accordingly.

Request To Reference Latest Service Information and Provide Credit for Previous Revision

Piaggio requested that paragraph (g)(3) of the proposed AD be updated to reference Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021, which is the latest service information. In addition, Piaggio requested that the Credit for Previous Actions specified in paragraph (h) of the proposed AD be revised to include Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019.

The FAA agrees with referencing Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021, in the actions required by paragraph (g)(3) of this AD. This is in addition to Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019. Because the FAA is referencing both in paragraph (g)(3) of this AD, no change to the Credit for Previous Actions specified in paragraph (h) of this AD is necessary. The final rule has been changed to reference Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021, in paragraph (g)(3) of this AD.

Conclusion

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 and service information referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for the changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019; Piaggio Aero Industries S.p.A. in A.S. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021; and Piaggio Aero Industries Service Bulletin S.p.A. A.S. No. 80–0457, Revision 1, dated February 12, 2020. This service information specifies procedures for modifying the TAT heater circuit in order to inhibit its engagement on the ground when the pitot heater is turned on. These documents are distinct because they apply to airplanes in different configurations.

The FAA reviewed Piaggio Aviation P.180 AVANTI II/EVO Temporary Change No. 79, dated September 17, 2018, which revises the Limitations and Normal Procedures sections of the existing AFM to include updated procedures for airplane operation when the modification for inhibition of the TAT heater (on ground) has been installed.

The FAA also reviewed Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019, which revises the Emergency and Normal Procedures sections of the existing AFM to include additional procedures to avoid air data computer failure due to water trapped and frozen in pitot lines.

This service information 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.

Other Related Service Information

The FAA reviewed Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017; Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 0, dated May 30, 2017; Piaggio Aero Industries S.p.A Service Bulletin No. 80–0425, Revision 1, dated December 15, 2017; and Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 2, dated June 4, 2018. This service information specifies procedures for replacing the Messier-Dowty nose and main landing gear and steering system with a Magnaghi nose and main landing gear and Eaton steering system.

The FAA also reviewed Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 0, dated August 10, 2017. This service information specifies procedures for modifying the TAT heater circuit in order to inhibit its engagement on the ground when the pitot heater is turned on.

Differences Between This AD and the MCAI

The MCAI requires informing all flight crews of the AFM revisions and operating accordingly thereafter, and this AD does not because these actions are already required by FAA operating regulations.

Costs of Compliance

The FAA estimates that this AD affects 101 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Modify TAT probe heater electrical circuit.	42 work-hours × $85 per hour = $3,570.	Up to $3,632	Up to $7,202	Up to $496,938 (69 airplanes).

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Revise AFM	1 work-hour × $85 per hour = $85.	Not Applicable	$85	$8,585 (101 airplanes).

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

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

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

(3) Will 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 Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 adding the following new airworthiness directive:

2022–19–07 Piaggio Aviation S.p.A.: Amendment 39–22176; Docket No. FAA–2022–0452; Project Identifier MCAI–2021–01356–A.

(a) Effective Date

This airworthiness directive (AD) is effective November 3, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piaggio Aviation S.p.A. Model P–180 airplanes, all serial numbers (S/Ns), certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3411, Pitot/Static System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as accumulation of water and subsequent freezing in the pitot-tube. The FAA is issuing this AD to prevent blockage of the pitot-tube. The unsafe condition, if not addressed, could result in temporary air data indications failure, which could result in loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) For all airplanes: Within 30 days after the effective date of this AD, revise the existing airplane flight manual (AFM) for your airplane by adding into the Emergency Procedures and Normal Procedures sections the information in Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019; or by incorporating into the Limitations and Normal Procedures sections the information in Piaggio Aviation P.180 Avanti II/EVO Temporary Change No. 79, dated September 17, 2018; as applicable to your airplane S/N. Using a different document with language identical to that in Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019; or Piaggio Aviation P.180 Avanti II/EVO Temporary Change No. 79, dated September 17, 2018; is acceptable for compliance with this requirement.

(2) For airplanes identified in paragraph (g)(2)(i) and (ii) of this AD: Within 660 hours time-in-service (TIS) after the effective date of this AD or 24 months after the effective date of this AD, whichever occurs first, modify the total air temperature (TAT) probe heater electrical circuit by following the Accomplishment Instructions, paragraphs (6) through (27), in Piaggio Aero Industries S.p.A. A.S. Service Bulletin No. 80–0457, Revision 1, dated February 12, 2020.

(i) S/N 1105, if Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017, is not incorporated.

(ii) S/Ns 1106 through 1234 inclusive, if Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425 up to Revision 2 is not incorporated.

(3) For airplanes identified in paragraphs (g)(3)(i) through (iii) of this AD: Within 660 hours TIS after the effective date of this AD or 24 months after the effective date of this AD, whichever occurs first, modify the TAT probe heater electrical circuit by following the Accomplishment Instructions, Paragraphs (6) through (21), in Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019, or Accomplishment Instructions, paragraphs (6) through (21) and (25), in Piaggio Aero Industries S.p.A. in A.S. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021.

(i) S/Ns 1002, 3001, 3003, 3004, 3006, and 3007.

(ii) S/N 1105, if Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017, is incorporated.

(iii) S/Ns 1106 through 1234 inclusive, if Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425 up to Revision 2 is incorporated.

(h) Credit for Previous Actions

This paragraph provides credit for the modification required by paragraph (g)(3) of this AD, if the modification was done before the effective date of this AD using Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 0, dated August 10, 2017.

(i) Alternative Methods of Compliance (AMOCs)

(1) 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 local Flight Standards District Office, as

appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov*.

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2019–0144, dated June 19, 2019, for more information. You may examine the EASA AD in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0452.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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 the AD specifies otherwise.

(i) Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019.

(ii) Piaggio Aero Industries S.p.A. in A.S. Service Bulletin No. 80–0430, Revision 2, dated July 20, 2021.

(iii) Piaggio Aero Industries Service Bulletin S.p.A. A.S. No. 80–0457, Revision 1, dated February 12, 2020.

(iv) Piaggio Aviation P.180 AVANTI II/EVO Temporary Change No. 79, dated September 17, 2018.

(v) Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019.

(3) For service information identified in this AD, contact Piaggio Aero Industries S.p.A, P180 Customer Support, Via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: (+39) 331 679 74 93; email: *technicalsupport@piaggioaerospace.it*.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on September 6, 2022.

Christina Underwood,

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

[FR Doc. 2022–20957 Filed 9–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0155; Project Identifier MCAI–2021–00585–T; Amendment 39–22075; AD 2022–12–03]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes; Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes; Model CL–600–2C11 (Regional Jet Series 550) airplanes; Model CL–600–2D15 (Regional Jet Series 705) airplanes; Model CL–600–2D24 (Regional Jet Series 900) airplanes; and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by reports of displayed headings changing from MAG to TRU with no pilot action, which may result in misleading heading information on both primary function displays (PFDs) and multi-function displays (MFDs), and misleading course information on flight management systems (FMSs). This AD requires amending the existing airplane flight manual (AFM) to provide the flightcrew with updated procedures for accurate heading and course information. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2022.

ADDRESSES: For service information identified in this final rule, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* internet *mhirj.com.* 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. It is also available on the internet at *regulations.gov* by searching for and locating Docket No. FAA–2022–0155.

Examining the AD Docket

You may examine the AD docket on the internet at regulations.gov by searching for and locating Docket No. FAA–2022–0155; 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 final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Thomas Niczky, Aerospace Engineer, Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2021–19, issued May 13, 2021 (TCCA AD CF–2021–19) (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes; Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes; Model CL–600–2C11 (Regional Jet Series 550) airplanes; Model CL–600–2D15 (Regional Jet Series 705) airplanes; Model CL–600–2D24 (Regional Jet Series 900) airplanes; and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. You may examine the MCAI in the AD docket at regulations.gov by searching for and locating Docket No. FAA–2022–0155.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes; Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes; Model CL–600–2C11 (Regional Jet Series 550) airplanes; Model CL–600–2D15 (Regional Jet Series 705) airplanes; Model CL–600–2D24 (Regional Jet Series 900) airplanes; and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM

published in the **Federal Register** on April 1, 2022 (87 FR 19026). The NPRM was prompted by reports of displayed headings changing from MAG to TRU with no pilot action, which may result in misleading heading information on both PFDs and MFDs, and misleading course information on FMSs. The NPRM proposed to require amending the existing AFM to provide the flightcrew with updated procedures for accurate heading and course information. The FAA is issuing this AD to prevent operation outside the terrain and obstacle protection provided in instrument procedure and route designs, which could result in reduced operational safety margins. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from the Air Line Pilots Association, International (ALPA) who supported the NPRM without change.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR part 51

MHI RJ Aviation ULC has issued the following service information, which provides a procedure for revising, among other procedures, the ''Uncommanded True Heading Indication.''

- Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, MHI RJ Model CL–600–2B19 AFM, CSP A–012, Volume 1, Revision 74, dated July 3, 2020.

Bombardier has issued the following service information, which provides a procedure for revising, among other procedures, the ''Uncommanded True Heading Indication.'' These documents are distinct since they apply to different airplane models.

- Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) and CL–600–2C11 (Series 550) AFM, CSP B–012, Revision 30, dated February 28, 2020.
- Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2D24 (Series 900) and Model CL–600–2D15 (Series 705) AFM, CSP C–012, Volume 1, Revision 24, dated March 27, 2020.
- Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2E25 (Series 1000) AFM, CSP D–012, Revision 23, dated February 14, 2020.

This service information 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.

Costs of Compliance

The FAA estimates that this AD affects 1,113 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$94,605

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

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

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

(3) Will 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 Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 adding the following new airworthiness directive:

2022–12–03 MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22075; Docket No. FAA–2022–0155; Project Identifier MCAI–2021–00585–T.

(a) Effective Date

This airworthiness directive (AD) is effective November 3, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (type certificate previously held by Bombardier, Inc.) airplanes, certificated in any category, as identified in paragraphs (c)(1) through (3) of this AD.

(1) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes equipped with inertial reference system (IRS) part number (P/N) 465020–0400–0400, 465020–0400–0401, 465020–0400–0402, or 465020–0400–0403.

(2) Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, Model CL–600–2C11 (Regional Jet Series 550) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, and Model CL–600–2D24 (Regional Jet Series 900) airplanes, equipped with IRS P/N 465020–0400–0401, 465020–0400–0402 or 465020–0400–0403.

(3) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, equipped with IRS P/N 465020–0400–0402 or 465020–0400–0403.

(d) Subject

Air Transport Association (ATA) of America Code 34; Navigation System.

(e) Unsafe Condition

This AD was prompted by reports of displayed headings changing from MAG to TRU with no pilot action, which may result in misleading heading information on both primary function displays (PFDs) and multi-function displays (MFDs), and misleading course information on flight management systems (FMSs). The FAA is issuing this AD to prevent operation outside the terrain and obstacle protection provided in instrument procedure and route designs, which could result in reduced operational safety margins.

(f) Compliance

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

(g) Amend Existing Airplane Flight Manual (AFM)

Within 30 days after the effective date of this AD: Revise the existing AFM to incorporate the information specified in Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, of the applicable AFM identified in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) – *AFM Revision*

Airplane Model	AFM Title	AFM Revision/Date
CL-600-2B19	MHI RJ Model CL-600-2B19 AFM, CSP A-012, Volume 1	Revision 74, dated July 3, 2020
CL-600-2C10 and -2C11	Bombardier CRJ Series Regional Jet Model CL-600-2C10 (Series 700, 701, 702) and CL-600-2C11 (Series 550) AFM, CSP B-012	Revision 30, dated February 28, 2020
CL-600-2D15 and -2D24	Bombardier CRJ Series Regional Jet Model CL-600-2D24 (Series 900) and Model CL-600-2D15 (Series 705) AFM, CSP C-012, Volume 1	Revision 24, dated March 27, 2020
CL-600-2E25	Bombardier CRJ Series Regional Jet Model CL-600-2E25 (Series 1000) AFM, CSP D-012	Revision 23, dated February 14, 2020

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district 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, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or MHI RJ Aviation ULC's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2021–19, issued May 13, 2021, for related information. This MCAI may be found in the AD docket on the internet at *regulations.gov* by searching for and locating Docket No. FAA–2022–0155.

(2) For more information about this AD, contact Thomas Niczky, Aerospace Engineer, Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7347; email *9-avs-nyaco-cos@faa.gov*.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) and CL–600–2C11 (Series 550) Airplane Flight Manual (AFM), CSP B–012, Revision 30, dated February 28, 2020.

(ii) Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2D24 (Series 900) and Model CL–600–2D15 (Series 705) AFM, CSP C–012,

Volume 1, Revision 24, dated March 27, 2020.

(iii) Section 05–15—Instrument Systems, Chapter 5, ABNORMAL PROCEDURES, Bombardier CRJ Series Regional Jet Model CL–600–2E25 (Series 1000) AFM, CSP D–012, Revision 23, dated February 14, 2020.

(iv) Section 05–15—Instrument Systems, of Chapter 5, ABNORMAL PROCEDURES, of MHI RJ Model CL–600–2B19 AFM, CSP A–012, Volume 1, Revision 74, dated July 3, 2020.

(3) For service information identified in this AD, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* internet *mhirj.com.*

(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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on June 2, 2022.

Christina Underwood,

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

Editorial note: This document was received for publication by the Office of the Federal Register on September 23, 2022.

[FR Doc. 2022–21014 Filed 9–28–22; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 220922–0196]

RIN 0691–AA93

Direct Investment Surveys: BE–12, Benchmark Survey of Foreign Direct Investment in the United States

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Final rule.

SUMMARY: The final rule amends regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the 2022 BE–12, Benchmark Survey of Foreign Direct Investment in the United States. The BE–12 survey is conducted every five years; the prior survey covered 2017. The benchmark survey covers the universe of foreign direct investment in the United States and is BEA's most detailed survey of such investment. For the 2022 BE–12 survey, BEA will make changes in data items collected, the design of the survey forms, and the reporting requirements for the survey to satisfy changing data needs and to improve data quality and the effectiveness and efficiency of data collection.

DATES: This final rule is effective October 31, 2022.

FOR FURTHER INFORMATION CONTACT: Kirsten Brew, Chief, Multinational Operations Branch, Direct Investment Division (BE–49), Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Road, Washington, DC 20233; phone (301) 278–9152; or via email at *Kirsten.Brew@bea.gov.*

SUPPLEMENTARY INFORMATION: This final rule amends 15 CFR part 801 to set forth the reporting requirements for the BE–12, Benchmark Survey of Foreign Direct Investment in the United States. Under this final rule 15 CFR 801.10 is modified to clarify the timing of this benchmark survey. The next BE–12 survey will apply to the 2022 fiscal reporting year, and will be conducted once every five years thereafter, for reporting years ending in 2 and 7.

BEA conducts the BE–12 survey under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The BE–12 survey covers the universe of foreign direct investment in the United States in terms of value and is BEA's most detailed survey of such investment. Foreign direct investment in the United States is defined as the ownership or control, directly or indirectly, by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise or an equivalent interest in an unincorporated U.S. business enterprise, including a branch.

The purpose of the BE–12 survey is to obtain universe data on the financial and operating characteristics of U.S. affiliates and on positions and transactions between U.S. affiliates and their foreign parent groups (which are defined to include all foreign parents and foreign affiliates of foreign parents). These data are needed to measure the size and economic significance of foreign direct investment in the United States, measure changes in such investment, and assess its impact on the U.S. economy. Such data are generally found in enterprise-level accounting records of respondent companies. These data are used to derive current universe estimates of direct investment from sample data collected in other BEA surveys in non-benchmark years. In particular, they serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions, international investment position, and national income and product accounts, and for annual estimates of the foreign direct investment position in the United States and of the activities of the U.S. affiliates of foreign companies.

Description of Changes

The final rule amends the regulations (15 CFR part 801) and the survey forms for the BE–12 survey. These amendments include changes in data items collected, the design of the survey forms, and the reporting requirements for the survey.

BEA adds, deletes, and modifies some items on the BE–12 survey forms. The following items will be added to the BE–12 survey:

(1) A question to collect the city of each foreign parent and ultimate beneficial owner (UBO) on all forms.

(2) The balance sheet and income statement sections on the BE–12A form will be modified to separately collect the investment in, and income from, (a) ''unconsolidated U.S. affiliates'' and (b) ''foreign entities,'' which were previously collected as a combined total.

(3) Supplemental sections A and B, which collect identification information on business enterprises owned by the U.S. affiliate, will be modified on all BE–12 forms to request more information on the reasons the U.S. business enterprises changed since the last report. This will include options for ''newly acquired'' or ''newly established'' if an enterprise is being reported on a supplement for the first time, and options to report U.S. business enterprises that had a name change, were sold, merged or liquidated. A follow-up question will be added requesting the date of the corporate change for new enterprises.

(4) Questions will be added on the BE–12A form to collect sales data for certain service types where there is no clear link between the industry of sales and the type of services supplied. These service types are (1) intellectual property (IP) rights and (2) advertising.

(5) Questions will be added to collect sales data on the BE–12A form related to the provision of selected services generally recognized as prevalent in the digital economy. These selected services are (1) cloud computing and data storage and (2) digital intermediation

services. In addition, checkboxes will be added to the BE–12A for respondents to identify the percentage of their sales of services delivered remotely, sales of services that were digitally ordered, and sales of goods that were digitally ordered, along with checkboxes to identify if this information was sourced from their accounting records or from recall/general knowledge.

The final rule also eliminates the following items from the benchmark survey:

(1) Expensed petroleum and mining expenditures from the BE–12A form.

(2) Commercial property from the state schedule of the BE–12A and BE–12B forms.

(3) Part III of the BE–12A and BE–12B forms, which collects information on investment and transactions between the U.S. affiliate and the affiliated foreign group, will be scaled back to include only the following items:

(1) Foreign parent ownership and classification information

(2) A question on reverse investment

(3) Intercompany debt balances for U.S. affiliates with less than $60 million in assets, sales, or net income.

The final rule will also modify the survey forms to improve question wording, layout, and instructions.

On July 1, 2022, BEA published a notice of proposed rulemaking that set forth revised reporting criteria for the BE–12, Benchmark Survey of Foreign Direct Investment in the United States (87 FR 39411). No comments on the proposed rule were received.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

Paperwork Reduction Act

The collection of information in this final rule was submitted to the Office of Management and Budget (OMB) pursuant to the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520 (PRA). OMB approved the information collection for the 2022 Benchmark Survey of Foreign Direct Investment in the United States under OMB control number 0608–0042. Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection displays a currently valid OMB control number.

The BE–12 survey is expected to result in the filing of reports from approximately 26,400 U.S. affiliates. The respondent burden for this collection of information will vary from one company to another. The estimated average time per respondent is 10.5 hours, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, the total respondent burden for this survey is estimated at 276,441 hours, compared to 249,625 hours for the previous (2017) benchmark survey. An increase in the number of foreign-owned companies accounts for nearly all of the increase in the estimated respondent burden, while the addition of new questions and the deletion of previous questions had a marginal impact on the estimated respondent burden.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the final rule should be sent to both BEA via email at *Kirsten.Brew@bea.gov,* and OMB, Office of Information and Regulatory Affairs (OIRA), Paperwork Reduction Project 0608–0042, Attention PRA Desk Officer for BEA, via email at *OIRA_Submission@omb.eop.gov.*

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified at the proposed rule stage to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding the certification or the economic impact of the rule. Therefore, a final regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 15 CFR Part 801

Economic statistics, Foreign investment in the United States, International transactions, Multinational enterprises, Penalties, Reporting and recordkeeping requirements.

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA amends 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.10 to read as follows:

§ 801.10 Rules and regulations for BE–12, Benchmark Survey of Foreign Direct Investment in the United States.

A BE–12, Benchmark Survey of Foreign Direct Investment in the United States, will be conducted once every five years and covers years ending in 2 and 7. BEA will describe the proposed information collection in a public notice and will solicit comments accounting to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501–3520). All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 and 801.2 and 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–12 survey are given in paragraphs (a) through (e) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–12, Benchmark Survey of Foreign Direct Investment in the United States, contained in this section, whether or not they are contacted by BEA. Also, a person, or their agent, contacted by BEA about reporting in this survey must respond in writing pursuant to this section. This may be accomplished by filing a properly completed BE–12 report (BE–12A, BE–12B, BE–12C, or BE–12 Claim for Not Filing).

(b) *Who must report.* A BE–12 report is required for each U.S. affiliate (except certain private funds as described in paragraphs (b)(1) through (3) of this section), that is, for each U.S. business enterprise in which a foreign person (foreign parent) owned or controlled, directly or indirectly, 10 percent or more of the voting securities in an

incorporated U.S. business enterprise, or an equivalent interest in an unincorporated U.S. business enterprise, at the end of the business enterprise's fiscal year that ended in the calendar year covered by the survey. Certain private funds are exempt from reporting on the BE–12 survey. If a U.S. business meets ALL of the following 3 criteria, it is not required to file any BE–12 report except to indicate exemption from the survey if contacted by BEA:

(1) The U.S. business enterprise is a private fund;

(2) The private fund does not own, directly or indirectly through another business enterprise, an ''operating company''—*i.e.,* a business enterprise that is not a private fund or a holding company—in which the foreign parent owns at least 10 percent of the voting interest; and

(3) If the foreign parent owns the private fund indirectly (through one or more other U.S. business enterprises), there are no U.S. ''operating companies'' between the foreign parent and the indirectly-owned private fund.

(c) *Forms to be filed.* (1) Form BE–12A must be completed by a U.S. affiliate that was majority-owned by one or more foreign parents (for purposes of this survey, a ''majority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate exceeds 50 percent) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the following three items for the U.S. affiliate (not just the foreign parent's share) was greater than $300 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey:

(i) Total assets (do not net out liabilities);

(ii) Sales or gross operating revenues, excluding sales taxes; or

(iii) Net income after provision for U.S. income taxes.

(2) Form BE–12B must be completed by:

(i) A majority-owned U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than $60 million (positive or negative) but none of these items was greater than $300 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(ii) A minority-owned U.S. affiliate (for purposes of this survey, a ''minority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate is 50 percent or less) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than $60 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey .

(3) Form BE–12C must be completed by a U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, none of the three items listed in paragraph (c)(1) of this section for a U.S. affiliate (not just the foreign parent's share), was greater than $60 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(4) Any U.S. person that is contacted by BEA concerning the BE–12 survey, but is not subject to the reporting requirements, must file a BE–12 Claim for Not Filing. The requirement in this paragraph (c)(4) is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(d) *Aggregation of real estate investments.* All real estate investments of a foreign person must be aggregated for the purpose of applying the reporting criteria. A single report form must be filed to report the aggregate holdings, unless written permission has been received from BEA to do otherwise. Those holdings not aggregated must be reported separately on the same type of report that would have been required if the real estate holdings were aggregated.

(e) *Due date.* A fully completed and certified Form BE–12A, BE–12B, BE–12C, or BE–12 Claim for Not Filing is due to be filed with BEA not later than May 31 of the year after the year covered by the survey (or by June 30 for reporting companies that use BEA's eFile system).

[FR Doc. 2022–21113 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 220923–0197]

RIN 0691–AA92

Direct Investment Surveys: BE–13, Survey of New Foreign Direct Investment in the United States

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States (''BE–13 survey''). The BE–13 survey collects information on the acquisition or establishment of U.S. business enterprises by foreign investors, and information on expansions by existing U.S. affiliates of foreign companies. The data collected through the survey are used to measure the amount of new foreign direct investment in the United States and ensure complete coverage of BEA's other foreign direct investment statistics. BEA will change the reporting requirements of the survey to reduce respondent burden, simplify reporting, and increase the efficiency of the data collection. This mandatory BE–13 survey is required from persons subject to the reporting requirements, whether or not they are contacted by BEA.

DATES: This final rule is effective October 31, 2022.

FOR FURTHER INFORMATION CONTACT: Ricardo Limes, Chief, Direct Transactions and Positions Branch (BE–49NI), Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Road, Washington, DC 20233; email *Ricardo.limes@bea.gov* or 301–278–9659.

SUPPLEMENTARY INFORMATION: The BE–13, Survey of New Foreign Direct Investment in the United States, is a mandatory survey conducted by BEA under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The purpose of the BE–13 survey is to collect data on the acquisition or establishment of U.S. business enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish a new facility where business is conducted. The data collected on the survey are used to measure the amount and

economic significance of new foreign direct investment in the United States and assess its impact on the U.S. economy. Foreign direct investment in the United States is defined as the ownership or control, directly or indirectly, by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch.

This final rule amends 15 CFR 801.7 to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States. Under this rule, persons subject to the reporting requirements of the BE–13, Survey of New Foreign Direct Investment in the United States, are required to respond, whether or not they are contacted by BEA.

Description of Changes

This final rule amends the regulations at 15 CFR part 801 by modifying § 801.7. Specifically, BEA changes the reporting requirements of form BE–13E, Fiscal Year End Cost Update for Projects Originally Reported on Forms BE–13B and BE–13D. The form collects updated cost information for greenfield investments—*i.e.,* establishments or expansions of U.S. businesses by foreign investors filed on BE–13B or BE–13D forms, respectively—and is required to be filed annually until the establishment or expansion of the U.S. business enterprise is complete.

BEA will limit the filing requirement of the BE–13E form to three years after the year the investment is initiated. BEA has found that this timeframe would be sufficient to collect the vast majority of the changes to total planned expenditures of greenfield investments and provide data users with insightful statistics on the ultimate cost of these investments. The change will reduce respondent burden and the BEA resources needed to continue to collect and process these updates, allowing BEA to focus resources on the featured statistics for more recent periods.

On June 28, 2022, BEA published a notice of proposed rulemaking that set forth revised reporting criteria for the BE–13, Survey of New Foreign Direct Investment in the United States (87 FR 38311). No comments were received on the proposed rule.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

Paperwork Reduction Act

The collection-of-information in this final rule was submitted to the Office of Management and Budget (OMB) pursuant to the requirements of the Paperwork Reduction Act (PRA). OMB approved the revision of the currently approved information collection under BE–13, Survey of New Foreign Direct Investment in the United States, OMB control number 0608–0035.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection displays a currently valid OMB control number.

The BE–13 survey is expected to result in the filing of approximately 3,027 reports from U.S. affiliates each year. The respondent burden for this collection of information is expected to vary because of differences in company structure, size, and complexity, but is estimated to average 1.1 hours per response. The burden includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, the total respondent burden for this survey is estimated at 3,027 hours, compared to 2,547 hours for the previous BE–13 survey estimate. The increase in burden hours is due to the increase in the overall number of respondents expected to file, partially offset by a reduction in the number of BE–13E forms expected to be filed.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule should be sent to both BEA via email at *Ricardo.Limes@bea.gov* and to OMB Office of Information and Regulatory Affairs (OIRA), Paperwork Reduction Project 0608–0035, Attention PRA Desk Officer for BEA, via email at *OIRA_Submission@omb.eop.gov.*

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, at the proposed rule stage that this action will not have a significant impact on a substantial number of small entities. No comments were received on that certification or on the economic impacts of this rule more generally. Therefore, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 801

Economic statistics, Foreign investment in the United States, International transactions, Penalties, Reporting and recordkeeping requirements.

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA amends 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.7 to read as follows:

§ 801.7 Rules and regulations for the BE–13, Survey of New Foreign Direct Investment in the United States.

The BE–13, Survey of New Foreign Direct Investment in the United States, is conducted to collect data on the acquisition or establishment of U.S. business enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish new facilities where business is conducted. Foreign direct investment is defined as the ownership or control by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch. BEA will describe the proposed information collection in a public notice and will solicit comments according to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501–3520). All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 and 801.2 and 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–13 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are

given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–13, Survey of New Foreign Direct Investment in the United States, contained herein, whether or not they are contacted by BEA. Also, a person, or their agent, who is contacted by BEA about reporting in this survey, either by sending them a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by filing the properly completed BE–13 report (BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption).

(b) *Who must report.* A BE–13 report is required of any U.S. business enterprise, except certain private funds, see exception in paragraph (b)(4) of this section, in which:

(1) A foreign direct investment in the United States relationship is created;

(2) An existing U.S. affiliate of a foreign parent establishes a new U.S. business enterprise, expands its U.S. operations, or acquires a U.S. business enterprise; or

(3) BEA requests a cost update (Form BE–13E) for a U.S. business enterprise that previously filed Form BE–13B or BE–13D.

(4) Certain private funds are exempt from reporting on the BE–13 survey. If a U.S. business enterprise is a private fund and does not own, directly or indirectly, 10 percent or more of another business enterprise that is not also a private fund or a holding company, it is not required to file any BE–13 report except to indicate exemption from the survey if contacted by BEA.

(c) *Forms to be filed.* Depending on the type of investment transaction, U.S. affiliates would report their information on one of five forms—BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption.

(1) Form BE–13A—report for a U.S. business enterprise when a foreign entity acquires a voting interest (directly, or indirectly through an existing U.S. affiliate) in that U.S. business enterprise including segments, operating units, or real estate; and

(i) The total cost of the acquisition is greater than $3 million; and

(ii) By this acquisition, the foreign entity now owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the acquired U.S. business enterprise.

(2) Form BE–13B—report for a U.S. business enterprise when it is established by a foreign entity or by an existing U.S. affiliate of a foreign parent; and

(i) The expected total cost to establish the new U.S. business enterprise is greater than $3 million; and

(ii) The foreign entity owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the new U.S. business enterprise.

(3) Form BE–13D—report for an existing U.S. affiliate of a foreign parent when it expands its operations to include a new facility where business is conducted, and the expected total cost of the expansion is greater than $3 million.

(4) Form BE–13E—report for a U.S. business enterprise that previously filed Form BE–13B or BE–13D. Form BE–13E collects updated cost information and will be collected annually for three years after the year of the establishment or expansion of the U.S. business enterprise.

(5) Form BE–13 Claim for Exemption—report for a U.S. business enterprise that:

(i) Was contacted by BEA but does not meet the requirements for filing Forms BE–13A, BE–13B, or BE–13D; or

(ii) Whether or not contacted by BEA, met all requirements for filing Forms BE–13A, BE–13B, or BE–13D except the $3 million reporting threshold.

(d) *Due date.* The BE–13 forms are due no later than 45 calendar days after the acquisition is completed, the new U. S. business enterprise is established, the expansion is begun, the cost update is requested, or a notification letter is received from BEA by a U.S. business enterprise that does not meet the filing requirements for the survey.

[FR Doc. 2022–21116 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–06–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 227

Regulation Crowdfunding, General Rules and Regulations

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 17 of the Code of Federal Regulations, Parts 200 to 239, revised as of April 1, 2022, amend § 227.201 by adding paragraph (z) to read as follows:

§ 227.201 Disclosure requirements.

* * * * *

(z) Any written communication or broadcast script provided in accordance with § 227.206 or, if within 30 days of the initial filing of the offering statement, § 230.241 of this chapter.

* * * * *

[FR Doc. 2022–21290 Filed 9–28–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 515, 516, 520, 522, 524, 529, and 558

[Docket No. FDA–2022–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy of the regulations.

DATES: This rule is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring

review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. Marketing exclusivity and patent information may be accessed in FDA's publication, ''Approved Animal Drug Products Online (Green Book)'' at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2022

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 10, 2022	131–675	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole), Type A Medicated Article.	Cattle	Supplemental approval to establish withdrawal periods in accordance with repartitioning of acceptable daily intake; and to add fourth-stage larval indications for certain endoparasites of cattle.	
January 13, 2022	141–546	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007.	SOLENSIA (frunevetmab injection), Injectable Solution.	Cats	Original approval for the control of pain associated with osteoarthritis.	FOI Summary.
January 20, 2022	141–547	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	ZORBIUM (buprenorphine transdermal solution), Transdermal Solution.	Cats	Original approval for the control of postoperative pain associated with surgical procedures.	FOI Summary.
January 25, 2022	200–707	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str.,1113 Sofia, Bulgaria.	TILMOVET AC (tilmicosin), Solution.	Swine	Original approval as a generic copy of NADA 141–361.	FOI Summary.
January 28, 2022	200–716	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	MIDAMOX for Dogs (imidacloprid and moxidectin), Topical Solution.	Dogs	Original approval as a generic copy of NADA 141–251.	FOI Summary.
February 7, 2022	200–665	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	INCREXXA 25 (tulathromycin injection), Injectable Solution.	Cattle and Swine.	Original approval as a generic copy of NADA 141–349.	FOI Summary.
February 7, 2022	200–717	Aurora Pharmaceutical, Inc,1196 Highway 3 South, Northfield, MN 55057–3009.	TIAGARD 12.5% (tiamulin hydrogen fumarate), Liquid Concentrate.	Swine	Original approval as a generic copy of NADA 140–916.	FOI Summary.
February 7, 2022	200–718	.....do	BARRIER for Dogs (imidacloprid and moxidectin), Topical Solution.	Dogs	Original approval as a generic copy of NADA 141–251.	FOI Summary.
February 9, 2022	200–715	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	AROVYN (tulathromycin injection), Injectable Solution.	Cattle and Swine.	Original approval as a generic copy of NADA 141–244.	FOI Summary.
March 11, 2022	200–720	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	ENROFLOX (enrofloxacin), Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 140–441.	FOI Summary.
March 23, 2022	200–723	.....do	TULIEVE (tulathromycin injection), Injectable Solution.	Cattle and Swine.	Original approval as a generic copy of NADA 141–244.	FOI Summary.
March 28, 2022	200–721	.....do	MIDAMOX for Cats (imidacloprid and moxidectin), Topical Solution.	Cats	Original approval as a generic copy of NADA 141–254.	FOI Summary.
March 28, 2022	200–722	.....do	FIROX (firocoxib), Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–230.	FOI Summary.
March 28, 2022	200–688	Virbac AH, Inc., P.O .Box 162059, Fort Worth, TX 76161.	TENOTRYL (enrofloxacin), Injectable Solution.	Cattle and Swine.	Original approval as a generic copy of NADA 141–068.	FOI Summary.
March 30, 2022	141–551	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland.	ZENALPHA (medetomidine and vatinoxan injection).	Dogs	Original approval for use as a sedative and analgesic to facilitate clinical examination, clinical procedures, and minor surgical procedures.	FOI Summary.

II. Withdrawals of Approval

Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601, has requested that FDA withdraw approval of NADA 140–908 for VET–METH Bolus, a bolus containing sulfamethazine for use in cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 520.2260a are amended to reflect this action.

Ridley USA, Inc., 111 W. Cherry St., Suite 500, Mankato, MN 56001, has requested that FDA withdraw approval of NADA 136–214 for VMS Bloat Blox, an oral dosage form containing polyoxyethylene (23) lauryl ether for use in beef and nonlactating dairy cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 520.1846 are amended to reflect this action.

III. Changes of Sponsorship

Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–129 for Isoflurane, USP and ANADA 200–467 for Sevoflurane to Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211. As provided in the regulatory text, the animal drug regulations in 21 CFR 529.1186 and 529.2110, respectively, are amended to reflect these changes of sponsorship.

IV. Change of Sponsor's Name and Address

Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478 has informed FDA that it has changed its name and address to Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505. As provided in the regulatory text, the animal drug regulations in § 510.600(c) (21 CFR 510.600(c)) are amended to reflect this change of a sponsor's name and address.

V. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- Section 510.600 is amended to remove the entry for Halocarbon Products Corp. from, and add Vetcare Oy to, the list of sponsors of approved applications. The entries for Mylan Institutional, Inc. and Norbrook Laboratories Ltd. are revised as well.
- 21 CFR 516.812 is amended to reflect a current drug labeler code for a use of enrofloxacin injectable solution in cattle.
- 21 CFR 520.88g is amended reflect a current sponsor drug labeler code and revised indications for use of tablets containing amoxicillin and clavulanate in dogs and cats.
- 21 CFR 520.530 is amended to conform to content codified for animal drugs available by veterinary prescription.
- 21 CFR 520.905a is amended to reflect revised conditions of use for fenbendazole suspension in horses.
- 21 CFR 520.928 is amended to reflect correct directions for administration of firocoxib chewable tablets in dogs.
- 21 CFR 520.1242a is amended to reflect revised indications for use of a levamisol powder in cattle and sheep.
- 21 CFR 520.1720a is amended to correct an error in the strength of approved phenylbutazone boluses.
- 21 CFR 520.1870 is amended to remove an undefined acronym in the conditions for use of praziquantel tablets.
- 21 CFR 520.1872 is amended to conform to content codified for animal drugs available by veterinary prescription.
- 21 CFR 520.2325a is amended to reflect instructions for use of sulfaquinoxaline powder and solution in poultry and cattle.
- 21 CFR 520.2598 is amended to reflect revised indications for use for trilostane capsules in dogs.
- 21 CFR 522.533 is amended to revise the indications for use of deslorelin injectable solution in mares.
- 21 CFR 522.2615 is amended to reflect revised human food safety warnings for tripelennamine injectable solution in cattle.
- 21 CFR 524.1001 is amended to correct a spelling error in the heading and specifications for fluralaner and moxidectin topical solution.
- 21 CFR 524.2098 is amended to reflect all sponsors of approved applications for selamectin topical solution in dogs and cats.
- 21 CFR 558.4 is amended in the Category II table to reflect the correct assay limits for Type C medicated feeds manufactured using nicarbazin powder.
- 21 CFR 558.128 is amended to reflect the class of cattle and incorporation level for single-ingredient and combination-drug medicated feeds containing chlortetracycline used for control of anaplasmosis in cattle.
- 21 CFR 558.633 is amended to clarify expiration dates for medicated feeds containing tylvalosin.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires **Federal Register** publication of ''notice[s]. . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 515 and 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 515, 516, 520, 522, 524, 529, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), remove the entry for ''Halocarbon

Products Corp.''; revise the entries for ''Mylan Institutional, Inc.'' and ''Norbrook Laboratories Ltd.''; and add in alphabetical order an entry for ''Vetcare Oy''; and

■ b. In the table in paragraph (c)(2), remove the entry for ''012164''; revise the entries for ''051079'' and ''055529''; and add in numerical order an entry for ''086155''.

The revisions and additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505	051079
* * * * * * *	
Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom	055529
* * * * * * *	
Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland	086155
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051079	Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505.
* * * * * * *	
055529	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.
* * * * * * *	
086155	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland.
* * * * * * *	

PART 515—MEDICATED FEED MILL LICENSE

■ 3. The authority citation for part 515 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. In § 515.10, revise paragraph (a) to read as follows:

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Form FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine at: *https://www.fda.gov/animal-veterinary/animal-food-feeds/medicated-feeds.*

* * * * *

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 5. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

§ 516.812 [Amended]

■ 6. In § 516.812, in paragraph (b), remove ''000859'' and in its place add ''058198''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 8. In § 520.88g, revise paragraphs (b)(2), (c)(1)(ii), and (c)(2)(ii) to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

* * * * *

(b) * * *

(2) Nos. 017033 and 069043 for use of tablets as in paragraph (c) of this section.

(c) * * *

(1) * * *

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus,* non-beta-lactamase-producing *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., and *E. coli.* Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

* * * * *

(2) * * *

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus,* non-beta-lactamase-producing *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli.*

* * * * *

§ 520.530 [Amended]

■ 9. In § 520.530, remove paragraph (c) and redesignate paragraph (d) as paragraph (c).

■ 10. In § 520.812, revise paragraphs (b)(1) and (3) to read as follows:

§ 520.812 Enrofloxacin.

* * * * *

(b) * * *

(1) No. 058198 for use of products described in paragraph (a) of this section.

* * * * *

(3) Nos. 055529 and 086101 for use of product described in paragraph (a)(2) of this section.

* * * * *

■ 11. In § 520.905a, revise paragraphs (e)(1)(ii) and (iii) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(1) * * *

(ii) *Indications for use.* For the treatment and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* species), small strongyles (*Cyathostomum* species, *Cylicocyclus* species, *Cylicostephanus* species, *Cylicodontophorus* species), pinworms (*Oxyuris equi*) and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Do not use in horses intended for human consumption.

* * * * *

■ 12. In § 520.928, revise the section heading and paragraphs (a), (b), and (c)(1)(i) to read as follows:

§ 520.928 Firocoxib.

(a) *Specifications*—(1) Each chewable tablet contains 57 or 227 milligrams (mg) firocoxib.

(2) Each tablet contains 57 mg firocoxib.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000010 and 055529 for use of products described in paragraph (a)(1) as in paragraph (c)(1) of this section; and

(2) No. 000010 for use of the product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) * * *

(1) * * *

(i) *Amount.* 5 mg/kg (2.27 mg/lb) body weight. Administer once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. Administer approximately 2 hours before soft tissue or orthopedic surgery.

* * * * *

■ 13. In § 520.1242a, revise paragraph (b)(3) to read as follows:

§ 520.1242a Levamisol powder.

* * * * *

(b) * * *

(3) No. 016592 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section.

* * * * *

■ 14. In § 520.1720a, revise paragraph (a) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) phenylbutazone. Each bolus contains 1, 2, or 4 g phenylbutazone.

* * * * *

§ 520.1846 [Removed]

■ 15. Remove § 520.1846.

§ 520.1870 [Amended]

■ 16. In § 520.1870, in paragraph (c)(2)(iii), in the third sentence, remove ''OTC'' and in its place add ''over the counter''.

■ 17. In § 520.1872, revise paragraph (c)(1)(iii) and add reserved paragraph (c)(2) to read as follows:

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

* * * * *

(c) * * *

(1) * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

■ 18. Revise § 520.2260a to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

(a) *Specifications.* Each oblet or bolus contains:

(1) 2.5, 5, or 15 grams sulfamethazine.

(2) 5 grams sulfamethazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section.

(1) No. 016592 for use of products described in paragraph (a)(1) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use.* (1) Oblets and boluses described in paragraph (a)(1) of this section:

(i) *Amount.* Administer as a single dose 100 milligrams per pound (mg/lb) of body weight the first day and 50 mg/lb of body weight on each following day.

(ii) *Indications for use.* (A) *Beef cattle and nonlactating dairy cattle.* For the treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), and coccidiosis (*Eimeria bovis* and *E. zurnii*).

(B) *Horses.* For the treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus* equi), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations.* Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Do not treat cattle within 10 days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(2) Boluses described in paragraph (a)(2) of this section:

(i) *Amount.* Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use.* (A) *Ruminating beef and dairy calves.* For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacillosis) caused by *Escherichia coli;* necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum;* bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(B) [Reserved]

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being

fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follow recommended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

■ 19. In § 520.2325a, revise paragraphs (c)(4)(iii) and (d) to read as follows:

§ 520.2325a Sulfaquinoxaline powder and solution.

* * * * *

(c) * * *

(4) * * *

(iii) In lieu of treatment as provided in paragraph (c)(4)(ii) of this section, administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations.* A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys, or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 20. In § 520.2455, revise paragraph (b)(3) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(3) Nos. 016592, 051072, 051311, and 061133 for product described in paragraph (a)(2) of this section.

* * * * *

■ 21. In § 520.2471, revise paragraph (b) to read as follows:

§ 520.2471 Tilmicosin.

* * * * *

(b) *Sponsors.* See Nos. 016592 and 058198 in § 510.600(c) of this chapter.

* * * * *

■ 22. In § 520.2598, revise paragraph (c)(2) to read as follows:

§ 520.2598 Trilostane.

* * * * *

(c) * * *

(2) *Indications for use.* For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism in dogs.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 23. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 24. In § 522.533, revise paragraphs (c)(1)(ii) and (c)(2)(ii) to read as follows:

§ 522.533 Deslorelin.

* * * * *

(c) * * *

(1) * * *

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters (mm) in diameter.

* * * * *

(c) * * *

(2) * * *

(ii) *Indications for use.* For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mm in diameter.

* * * * *

■ 25. In § 522.812, revise paragraph (b)(2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(2) Nos. 051311, 055529, 058005, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraphs (e)(2) and (3) of this section.

* * * * *

■ 26. Add § 522.1008 to read as follows:

§ 522.1008 Frunevetmab.

(a) *Specifications.* Each milliliter (mL) of solution contains 7 milligrams (mg) frunevetmab.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Cats*—(i) *Amount.* Administer once a month by subcutaneous injection the full contents of one or two 1-mL vials to achieve a minimum dosage of 0.45 mg/lb (1 mg/kg) body weight.

(ii) *Indications for use.* For the control of pain associated with osteoarthritis in cats.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

■ 27. Add § 522.1338 to read as follows:

§ 522.1338 Medetomidine and vatinoxan.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) medetomidine hydrochloride and 10 mg vatinoxan hydrochloride.

(b) *Sponsor.* See No. 086155 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by intramuscular injection a dose based on body surface area (BSA). Calculate the dose using 1 mg medetomidine per square meter ($/m^2$) BSA or use the dosing table provided in labeling.

(2) *Indications for use.* For use as a sedative and analgesic in dogs to facilitate clinical examination, clinical procedures, and minor surgical procedures.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 28. In § 522.2615, revise paragraph (d)(3)(iii) to read as follows:

§ 522.2615 Tripelennamine.

* * * * *

(d) * * *

(3) * * *

(iii) *Limitations.* Milk taken during treatment and for 24 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 4 days following the last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 29. In § 522.2630, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(1) Nos. 000061, 013744, 051311, 054771, 055529, 058198, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Nos. 013744, 051311, 054771, and 058198 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 30. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 31. Add § 524.230 to read as follows:

§ 524.230 Buprenorphine.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 milligrams (mg) buprenorphine. The drug is supplied in tubes containing 0.4 mL (8 mg) or 1.0 mL (20 mg).

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer topically to the dorsal cervical area at the base of the skull a single dose of 1.2 to 3.1 mg/lb

(2.7 to 6.7 mg/kg) approximately 1 to 2 hours before surgery.

(2) *Indications for use.* For the control of postoperative pain associated with surgical procedures in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Buprenorphine is a Schedule III controlled substance.

■ 32. In § 524.1001, revise the section heading and paragraph (a) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

(a) *Specifications.* Each milliliter of solution contains 280 milligram (mg) fluralaner and 14 mg moxidectin. Each individually packaged tube contains either 112.5 mg fluralaner and 5.6 mg moxidectin; 250 mg fluralaner and 12.5 mg moxidectin; or 500 mg fluralaner and 25 mg moxidectin.

* * * * *

■ 33. In § 524.1146, revise paragraphs (b)(1) and (2) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(1) Nos. 017030, 051072, 055529, 058198, and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030, 051072, 055529, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

■ 34. In § 524.2098, revise paragraph (b) to read as follows:

§ 524.2098 Selamectin.

* * * * *

(b) *Sponsors.* See Nos. 051072, 054771, 055529, 061133, and 061651 in § 510.600(c) of this chapter.

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 35. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 36. In § 529.1186, revise paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 017033, 054771, 065085, and 066794 in § 510.600(c) of this chapter.

* * * * *

■ 37. In § 529.2110, revise paragraph (b) to read as follows:

§ 529.2110 Sevoflurane.

* * * * *

(b) *Sponsors.* See Nos. 017033, 054771, and 066794 in § 510.600(c) of this chapter.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 38. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

■ 39. In § 558.4, in paragraph (d), in the ''Category II'' table, revise the entry for ''Nicarbazin (powder)'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent [1] type A	Type B maximum (100x)	Assay limits percent [1] type B/C [2]
* * *	*	* * *	*
Nicarbazin (powder)	96–104	9.08 g/lb (2.00%)	85–115/80–120
* * *	*	* * *	*

* * * * * * *.

* * * * *

■ 40. In § 558.128, revise paragraphs (e)(4)(iii) and (xli) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * *	*	* *	*	*
(iii) to provide 0.5 mg/lb of body weight daily.		Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 0.5 mg per pound of body weight daily. Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
(xli) 25 to 2,800 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate.	Growing beef heifers fed in confinement for slaughter under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
* *	*	* *	*	*

* * * * * * *.

* * * * *

■ 41. In § 558.258, revise paragraph (e)(1), paragraph (e)(2) table column headings, and paragraphs (e)(2)(i) and (e)(3) through (5) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(1) * * *

Fenbendazole grams per ton	Combination grams per ton	Indications for use	Limitations	Sponsor
(i) 14.5		Growing turkeys: For the treatment and control of gastrointestinal worms: roundworms, adults and larvae (*Ascaridia dissimilis*); cecal worms, adults and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	000061
(ii) [Reserved]				

(2) *Swine.*

Fenbendazole grams per ton	Combination grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300		Swine: For the treatment and control of Lungworms: adult (*Metastrongylus apri* and *M. pudendotectus*); Gastrointestinal worms: adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis);* and Kidney worms: adult and larvae (*Stephanurus dentatus*).	Feed as the sole ration to provide 9 mg/kg of body weight (4.08 mg/lb) over a period of 3 to 12 consecutive days. Swine must not be slaughtered for human consumption within 4 days following last treatment with this drug product.	000061
*	*	*	*	*	*	*

(3) *Cattle.*

Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
(i) 200 to 1,000	Dairy and beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed as the sole ration for 1 day to provide 5 mg/kg body weight (2.27 mg/lb). Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(ii) [Reserved]			

(iii) *Top dress medicated feed*—(A) *Proprietary formulas.* The following feed can be manufactured only per an approved proprietary formula and specifications:

Fenbendazole concentration	Indications for use	Limitations	Sponsor
(*1*) 2.27 g/lb	Beef and dairy cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata and C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed as a top dress for 1 day to provide 5 mg/kg body weight (2.27 mg/lb). Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*2*) [Reserved]			

(B) [Reserved]

(iv) *Free-choice medicated feeds*—(A) *Proprietary formulas (21 CFR 510.455(e)(2)).* The following feeds can be manufactured only per an approved proprietary formula and specifications:

Fenbendazole concentration	Indications for use	Limitations	Sponsor
(*1*) 12,100 g/ton mineral	Beef cattle on pasture: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free-choice at the rate of 0.0375 lb per 100 pounds of body weight over a 3- to 6-day period to provide a total of 2.27 mg fenbendazole per pound of body weight. Not for use in dairy cattle. Beef cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*2*) 2.27 g/lb mineral	Beef cattle on pasture: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free-choice at the rate of 0.10 lb (1.6 oz) per 100 pounds of body weight over a 3- to 6-day period, to deliver a total of 2.27 mg fenbendazole per pound of body weight. Not for use in dairy cattle. Beef cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061

(B) *Published formulas (§ 510.455(e)(1) of this chapter).* The following feeds can be manufactured only per one of the formulas and specifications published below:

(*1*) *Amount.* 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient [1]	Percent	International Feed No.
(*i*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(*ii*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695
Potassium iodide	0.01	6–03–759
Fenbendazole 20% Type A article	2.10	n/a
(*iii*) Free-choice, liquid Type C feed [2]:		
Cane molasses [3]	80.902	4–13–251
Water	9.36	n/a
Urea solution, 55%	7.05	5–05–707
Phosphoric acid 75% (feed grade)	2.00	6–03–707
Xantham gum	0.20	8–15–818
Trace minerals [4]	0.20	n/a
Vitamin premix [4]	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1] Formulation modifications require FDA approval prior to marketing. Selenium is not approved for use in the liquid, free-choice formulations described in paragraph (e)(3)(iv)(B) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (*see* 21 CFR 573.920).

[2] The labeling for the liquid free-choice Type C medicated feed must bear an expiration date of 12 weeks after the date of manufacture.
[3] The percentage of cane molasses and water in the formulation may be adjusted as needed to bring the brix value of the molasses to the industry standard of 79.5 brix.
[4] The contents of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds.

(*2*) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(*3*) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

(4) *Horses.*

Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), and pinworms (*Oxyuris equi*); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (*Parascaris equorum*).	Feed at the rate of 0.1 lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Do not use in horses intended for human consumption.	000061
(ii) [Reserved]			

(5) *Zoo and wildlife animals.*

Species/Class	Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
(i) Feral swine (*Sus scrofa*):.	90 to 325	For the treatment and control of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*).	Use as a complete feed at a rate to provide 3 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	50 to 300	For the treatment and control of small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.).	Use as a complete feed at a rate to provide 2.5 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(iii) Rocky mountain bighorn sheep (*Ovis c. canadensis*).	375 to 1,000	For the treatment and control of *Protostrongylus* spp..	Use as a complete feed at a rate to provide 10 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

* * * * *

§ 558.633 [Amended]

■ 42. In § 558.633, in paragraph (d)(3), remove the first sentence.

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20836 Filed 9–28–22; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9966]

RIN 1545–BQ17

User Fees Relating to Enrolled Agents and Enrolled Retirement Plan Agents

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: These final regulations amend existing regulations relating to user fees for enrolled agents and enrolled retirement plan agents. The final regulations increase the renewal user fee for enrolled retirement plan agents from $67 to $140. In addition, the final regulations increase both the enrollment and renewal of enrollment user fees for enrolled agents from $67 to $140. These regulations affect individuals who are or apply to become enrolled agents and individuals who are enrolled retirement plan agents. The Independent Offices Appropriation Act of 1952 authorizes charging user fees.

DATES:

Effective date: These regulations are effective October 31, 2022.

Applicability date: For the date of applicability, see §§ 300.5(d), 300.6(d), and 300.09(d).

FOR FURTHER INFORMATION CONTACT: Mark Shurtliff at (202) 317–6845 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the regulations in 26 CFR part 300—User Fees. On March 1, 2022, a notice of proposed rulemaking (REG–114209–21) and notice of public hearing was published in the **Federal Register** (87 FR 11366). The document proposed amending the regulations relating to the user fees for enrolled agents and enrolled retirement plan agents. The document proposed increasing the amount of the renewal user fee for enrolled retirement plan agents from $67 to $140. In addition, the document proposed increasing both the enrollment and renewal of enrollment user fees for enrolled agents from $67 to $140. The document contains a detailed explanation of the legal background and user fee calculations regarding the amendments to these regulations.

Six comments responding to the notice of proposed rulemaking were received, including comments from the National Association of Enrolled Agents (NAEA). On May 3, 2022, representatives from the NAEA, Department of the Treasury (Treasury Department), the IRS, and the Small Business Administration (SBA), held a teleconference to listen to NAEA's comments about the proposed rulemaking. In addition, two requests to speak at the scheduled public hearing were received. A public hearing was held on May 11, 2022. After consideration of the written comments, teleconference comments, and testimony at the public hearing, the Treasury Department and the IRS have decided to adopt without modification the regulations proposed by the notice of proposed rulemaking.

Summary of Comments

The six comments submitted in response to the notice of proposed rulemaking and a summary of the teleconference comments are available at *www.regulations.gov* or upon request. Some of the comments that were submitted did not seek modification or clarification of the user fee as set forth in the proposed regulations. One commenter expressed concern with how the special enrollment examination for enrolled agents (EA SEE) is being administered. The commenter also recommended using the user fees in these regulations to provide resources for tax professionals that would improve the service they provide to their clients. The user fees in these regulations are not used by the Treasury Department or the IRS to administer the EA SEE, or to provide resources for tax professionals that improve the service they provide to their clients. Therefore, comments regarding the EA SEE and additional resources identified by the commenter are outside the scope of these regulations. Another commenter suggested that the IRS should raise the amount of the user fee to apply for or renew a preparer tax identification number (PTIN) in order to (1) lower the cost of user fees relating to enrolled agents and (2) encourage more individuals to become enrolled agents. These regulations do not relate to the PTIN user fee or the PTIN program. Therefore, comments regarding the PTIN program and related user fees are outside the scope of these regulations. Finally, one commenter suggested that it is inconsistent for the IRS to charge user fees in order to administer the enrollment and renewal of enrollment program but not charge user fees for other programs (for example, participation in the Annual Filing Season Program). Again, comments regarding programs other than the enrollment and renewal of enrollment program are outside the scope of these regulations. The summary of comments below addresses those comments that make recommendations concerning or seeking clarification of the user fees set forth in the proposed regulations relating to the user fees for enrolled agents and enrolled retirement plan agents.

A. Amount of User Fees

Four commenters expressed concern with the overall amount of the proposed enrollment and renewal of enrollment user fees and requested information regarding why the user fees are required.

The Independent Offices Appropriation Act of 1952 (IOAA) (31 U.S.C. 9701) authorizes each agency to promulgate regulations establishing the charge for services provided by the agency. The IOAA states that the services provided by an agency should be self-sustaining to the extent possible. 31 U.S.C. 9701(a). The IOAA provides that user fee regulations are subject to policies prescribed by the President, which are currently set forth in the Office of Management and Budget (OMB) Circular A–25 (OMB Circular), 58 FR 38142 (July 15, 1993).

Section 6a(1) of OMB Circular A–25 states that when a service offered by a Federal agency provides special benefits to identifiable recipients beyond those accruing to the general public, the agency should establish a user fee to recover the full cost of providing the service. An agency that seeks to impose a user fee for government-provided services must calculate the full cost of providing those services.

In accordance with OMB Circular A–25, the IRS Return Preparer Office (RPO) completed its 2021 biennial review of the enrollment and renewal of enrollment user fees associated with enrolled agents and enrolled retirement plan agents. As discussed in the notice of proposed rulemaking, during its review the RPO took into account the increase in labor, benefits, and overhead costs incurred in connection with providing enrollment services to individuals who enroll or renew

enrollment as enrolled agents and renew enrollment as enrolled retirement plan agents since the user fee was last increased in 2019. The proposed increase took into account the additional staffing that allows the RPO to provide a higher quality of service to individuals seeking to enroll or renew enrollment. The RPO also took into account a reallocation of certain labor costs in their methodology. The RPO followed the generally accepted accounting principles established by the Federal Accounting Standards Advisory Board. The RPO determined that the full cost of administering the program for enrolled agents and enrolled retirement plan agents has increased from $67 to $140 per application for enrollment or renewal of enrollment. That amounts to a $73 increase per application for enrollment or renewal of enrollment. The enrollment user fee is a one-time cost, and renewal of enrollment user fees are due once every three years, so the increase amounts to an additional $24.33 per year.

B. OMB Circular A–25 Requirements

Two of the commenters stated that the IRS did not fully comply with OMB Circular A–25. Two of the commenters questioned whether the service related to the user fees in these regulations confers a special benefit on enrolled agents and enrolled retirement plan agents. One of the commenters indicated that the service the IRS provides under these regulations benefits the general public rather than a specific beneficiary (that is, enrolled agents and enrolled retirement plan agents). Finally, two of the commenters stated that OMB Circular A–25 allows for an exception to the user fee requirement.

The Treasury Department and the IRS disagree with the comments regarding OMB Circular A–25. Section 6a(1) of OMB Circular A–25 states that when a service offered by a Federal agency provides special benefits to identifiable recipients beyond those accruing to the general public, the agency should establish a user fee to recover the full cost of providing the service. An agency that seeks to impose a user fee for government-provided services must calculate the full cost of providing those services. Under OMB Circular A–25, a user fee should be set at an amount that recovers the full cost of providing a service, unless the OMB grants an exception. The full cost of providing a service includes both the direct and indirect costs of providing the service.

The IRS provides enrollment and renewal of enrollment services to specific, identifiable recipients: enrolled agents and enrolled retirement plan agents. An individual who has been granted enrollment as an enrolled agent or an enrolled retirement plan agent may practice before the IRS, including representing taxpayers. The IRS confers benefits on individuals who are enrolled agents or enrolled retirement plan agents beyond those that accrue to the general public by allowing them to practice before the IRS. Because the ability to practice before the IRS is a special benefit that does not accrue to the general public, the IRS charges a user fee to recover the full cost associated with administering the enrollment and renewal of enrollment program.

An agency is required to set the user fee at an amount that recovers the full cost of providing the service unless the agency requests, and the OMB grants, an exception to the full-cost requirement. Under section 6c(2) of OMB Circular A–25, the OMB may grant exceptions when the cost of collecting the fees would represent an unduly large part of the fee for the activity or when any other conditions exist that, in the opinion of the agency head, justifies an exception. When the OMB grants an exception, the agency does not collect the full cost of providing the service and must fund the remaining cost of providing the service from other available funding sources. Consequently, the agency subsidizes the cost of the service to the recipients of reduced-fee services even though the service confers a special benefit on those recipients who would otherwise be required to pay the full cost of receiving the benefit as provided by OMB Circular A–25. The cost of collecting the user fees in these regulations does not represent an unduly large part of the fee. In addition, the Treasury Department and the IRS have not identified any conditions that exist that would justify an exception to the full-cost requirement. Therefore, it is appropriate for the IRS to recover the full cost it incurs to provide enrollment and renewal of enrollment services to individuals seeking to practice before the IRS as enrolled agents or enrolled retirement plan agents.

C. Justification for Increasing the User Fees

One of the commenters expressed concern with the amount by which the user fees have increased since 2019. Specifically, user fees were increased from $30 to $67 in 2019, and the notice of proposed rulemaking for these final regulations proposed to increase the user fees from $67 to $140. The commenter questioned how the RPO's reallocation of labor costs could account for the increases.

The amount of the user fee increases can be explained, in part, by certain reallocations of labor costs and how other user fees have affected the user fees relating to the enrollment and renewal of enrollment program for enrolled agents and enrolled retirement plan agents. On September 30, 2010, the Treasury Department and the IRS published two final regulations in the **Federal Register**: (1) final regulations (TD 9501, 75 FR 60309) that required tax return preparers who prepare for compensation all or substantially all of a tax return or claim for refund to obtain a PTIN and (2) final regulations (TD 9503, 75 FR 60316) that required a user fee to apply for or renew a PTIN. Individuals applying for, or renewing, a PTIN were to be subject to Federal tax-compliance and suitability checks and were required to pay a $50 user fee (plus an additional amount payable directly to a third-party vendor) to obtain or renew a PTIN. All enrolled agents and certain enrolled retirement plan agents were required to obtain a PTIN as a condition of enrollment and renewal of enrollment. TD 9527, 76 FR 32286; Notice 2011–91, 2011–47 I.R.B. 792. On April 19, 2011, the Treasury Department and the IRS published in the **Federal Register** (76 FR 21805) a final regulation (TD 9523) that reduced the amount of the user fees for the initial enrollment and renewal of enrollment for enrolled agents and enrolled retirement plan agents from $125 to $30. The user fee to enroll or renew enrollment was reduced because certain procedures, including Federal-tax compliance and suitability checks, which were previously performed as part of the enrolled agent and enrolled retirement plan agent enrollment application process, were to be performed as part of the required process to obtain a PTIN.

As required by the IOAA and OMB Circular A–25, the RPO conducted a biennial review of the enrollment and renewal of enrollment user fees associated with enrolled agents and enrolled retirement plan agents in 2017. During its review the RPO took into account the increase in labor, benefits, and overhead costs incurred in connection with providing services to individuals who enroll or renew enrollment as enrolled agents and enrolled retirement plan agents since the user fee was changed in 2011. In addition, the RPO determined that costs associated with Federal tax-compliance checks and suitability checks on applicants for enrollment and renewal should be recovered as part of the user fee for administering the enrollment and

renewal of enrollment programs (and not the PTIN user fee). The 2017 biennial review also took into account new costs associated with administering the program for enrolled agents and enrolled retirement plan agents, including the costs of operating a dedicated toll-free helpline in the RPO for enrollment and renewal of enrollment matters. The RPO determined that the full cost of administering the program for enrolled agents and enrolled retirement plan agents had increased from $30 to $67 per application for enrollment or renewal of enrollment. On May 13, 2019, the Treasury Department and the IRS published in the **Federal Register** (84 FR 20801–01) a final regulation (TD 9858) that established the current $67 user fee per enrollment or renewal of enrollment. The user fee complied with the directive in OMB Circular A–25 to recover the full cost of providing a service that confers special benefits on identifiable recipients beyond those accruing to the general public.

The user fees for enrollment and renewal of enrollment were $125 prior to the RPO's reallocation of certain labor costs related to the PTIN user fee in 2011. The proposed user fee of $140 recovers many of the same costs associated with the RPO's administration of the enrollment and renewal of enrollment program that were recovered in the enrollment and renewal of enrollment user fees prior to the reallocation of certain labor costs to the PTIN user fee, as well as additional staffing and services the RPO currently provides associated with enrollment and renewal of enrollment. Even though the RPO has increased its staff to provide a higher quality of service, and now provides additional services, the user fee for enrollment and renewal of enrollment is only $15 more than the enrollment and renewal of enrollment fees in 2011.

One of the commenters expressed concern about the number of full-time equivalent (FTE) employees assigned to the enrollment and renewal of enrollment program, FTE activities, and the ratio of managers to staff employees. The commenter stated that there were 17 FTEs assigned to the enrollment and renewal of enrollment program, including three managers and 14 staff employees. The commenter questioned whether that number of managers and FTEs was necessary to administer the enrollment and renewal of enrollment program.

The employment and management figures cited by the commenter are not accurate. There are 14 employees assigned entirely to the enrollment and renewal of enrollment program, including two managers that oversee the 12 other employees. One of the managers is a director who oversees five FTEs, but only two of those FTEs are assigned fully to the enrollment and renewal of enrollment program (and whose salary, benefits, and associated overhead are charged to the enrollment and renewal of enrollment program). Because the director oversees three FTEs who are not fully assigned to the enrollment and renewal of enrollment program, not all of the director's salary is charged to the enrollment and renewal of enrollment program. The other manager is a frontline manager who oversees 10 FTEs, all of whom are dedicated entirely to the enrollment and renewal of enrollment program.

The IRS determines the cost of its services and the activities involved in producing them through a cost-accounting system that tracks costs to organizational units. The lowest organizational unit in the IRS's cost-accounting system is called a cost center. There are two cost centers related to the enrollment and renewal of enrollment program: the Policy and Management Cost Center and the Enrollment Cost Center. The Policy and Management Cost Center includes three FTEs: one director, one senior analyst, and one administrative assistant. The director oversees the entire enrollment and renewal of enrollment program. The senior analyst manages inventory, handles system administrator duties for the toll-free helpline, and is responsible for reporting requirements for the enrollment and renewal of enrollment program. The administrative assistant provides administrative support to the director and staff, processes mail (including applications, checks, and general correspondence), uploads mail to be distributed to legal instrument examiners, and other administrative support duties (including managing the director's calendar and filing personnel documents).

The Enrollment Cost Center includes one manager, one clerk, and nine legal instrument examiners. The manager is responsible for work assignments, work reviews, employee evaluations, leave approvals, and other managerial tasks. The clerk processes mail, prints and mails enrollment and renewal of enrollment certificates and cards, updates enrolled agent and enrolled retirement plan agent account information, makes electronic copies of paper documents, and provides clerical assistance with issuing notices to enrolled agents and enrolled retirement plan agents. The nine legal instrument examiners process enrollment and renewal of enrollment forms, make referrals to the RPO's suitability department for Federal tax-compliance checks and criminal background checks (if necessary), document findings and eligibility status in the RPO's case-tracking software, answer calls on the toll-free helpline, and respond to emails from enrolled agents and enrolled retirement plan agents. In addition, to improve the level of service for processing, the toll-free telephone operations staffing has increased, quality review programs have been implemented, and correspondence backlogs have been eliminated.

The RPO has determined that these managers and other employees are necessary to effectively administer the enrollment and renewal of enrollment program and provide high-quality service to individuals seeking to enroll or renew enrollment.

The same commenter also questioned a reallocation of costs that partially accounted for the proposed increased fee for enrollment or renewal of enrollment. This reallocation refers to a portion of oversight and support costs that had previously been recovered through other funding sources. During the biennial review, the RPO determined that these costs were associated with the enrollment and renewal of enrollment program and thus were appropriately recovered through the enrollment and renewal of enrollment user fees.

D. Impact of User Fees on Enrollment and Renewal of Enrollment of Enrolled Agents and Enrolled Retirement Plan Agents

Four of the commenters opined that the Treasury Department and the IRS should take into account that enrolled agents help improve the Federal tax system. For example, enrolled agents are required to take continuing education courses, which enable them to accurately prepare tax returns and efficiently resolve taxpayer disputes with the IRS. The four commenters expressed concern that the proposed user fee increases may discourage individuals from enrolling as enrolled agents or renewing their enrollment.

The Treasury Department and the IRS recognize the valuable service enrolled agents and enrolled retirement plan agents provide to taxpayers as well as the contributions they make to improving the Federal tax system. As discussed in Section A of this preamble, despite the service enrolled agents and enrolled retirement plan agents provide to taxpayers, OMB Circular A–25 states that when a service offered by a Federal agency provides special benefits to

identifiable recipients beyond those accruing to the general public, the agency should establish a user fee to recover the full cost of providing the service (unless the agency requests, and the OMB grants, an exception to the full-cost requirement). As discussed in Section B of this preamble, the IRS confers benefits on individuals who are enrolled agents and enrolled retirement plan agents beyond those that accrue to the general public by allowing them to practice before the IRS. The Treasury Department and the IRS comply with OMB Circular A–25 by charging user fees to recover the full cost of overseeing the enrollment and renewal of enrollment program. The Treasury Department and the IRS have not requested an exception from the OMB because there is no data that indicates that the user fee for enrollment or renewal of enrollment is cost prohibitive or that any other condition exists that justifies an exception.

E. Regulatory Flexibility Act (RFA) Compliance

One commenter stated that the Treasury Department and the IRS should have conducted an initial regulatory flexibility analysis pursuant to the RFA, based on the assumption that these regulations will have a significant economic impact on a substantial number of small entities. The commenter explained that it surveyed the enrolled agent community and found that 53 percent of enrolled agents are sole practitioners and 46 percent work for a firm. In the commenter's view, sole proprietorships should be considered small entities and the firms that employ enrolled agents (which sometimes reimburse enrolled agents for their user fees) are generally small businesses. Therefore, the commenter concluded that the user fees in these regulations would have a significant economic impact on a substantial number of small entities.

The Treasury Department and the IRS disagree that these regulations will have a significant economic impact on a substantial number of small entities. As discussed in the notice of proposed rulemaking, only individuals, not businesses, can be enrolled agents or enrolled retirement plan agents. Accordingly, the user fee primarily affects individuals who are enrolled agents, apply to become enrolled agents, or are enrolled retirement plan agents.

Since individuals are not ''small entities'' for purpose of the RFA, any economic impact of the user fees on small entities generally will occur only when an enrolled agent or enrolled retirement plan agent owns a small business or when a small business employs enrolled agents or enrolled retirement plan agents and reimburses them for their user fees.

Even if a substantial number of small businesses are affected by reimbursing enrolled agents or enrolled retirement plan agents for their user fees, a regulatory flexibility analysis would not be required because the economic impact on small entities is not significant. The economic impact on any small entities affected would be limited to paying, triennially, the $73 difference in cost between the $140 user fee and the previous $67 user fee (for each enrolled agent or enrolled retirement plan agent who a small entity employs and reimburses).

The RFA does not define the term ''significant economic impact;'' however, the SBA has provided guidance for government agencies on how to comply with the RFA, including determining whether a regulation will have a significant economic impact. The SBA's guidance is available at *https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf.* The SBA's guidance explains that one measure for determining the economic impact is the percentage of revenue or percentage of gross revenues affected. For example, if the cost of implementing a particular rule represents three percent of the profits in a particular sector of the economy and the profit margin in that industry is two percent of gross revenues (an economic structure that occurs in the food marketing industry, where profits are often less than two percent), the implementation of the proposal would drive many businesses out of business (all except the ones that beat a three percent profit margin). According to the SBA's guidance, the regulation in this example would have a significant economic impact.

The SBA's guidance further explains that the economic impact does not have to completely erase profit margins to be significant. For example, the implementation of a rule might reduce the ability of the firm to make future capital investment, thereby severely harming its competitive ability, particularly against larger firms. This scenario may occur in the telecommunications industry, where a regulatory regime that harms the ability of small companies to invest in needed capital will not put them out of business immediately, but over time may make it impossible for them to compete against companies with significantly larger capitalizations. The impact of that rule would then be significant for smaller telecommunications companies.

Finally, the SBA's guidance explains that other measures may be used. For example, the impact could be significant if the cost of the proposed regulation (a) eliminates more than 10 percent of the businesses' profits; (b) exceeds one percent of the gross revenues of the entities in a particular sector; or (c) exceeds five percent of the labor costs of the entities in the sector.

While data relevant to the SBA's guidance is limited, the Treasury Department and the IRS have carefully considered public information related to the economic impact of the proposed user fees. For example, Surgent, an organization that provides preparation courses for the EA SEE, states on its website at *https://www.surgent.com* that the average salary for an enrolled agent as of December 2021 is $59,020. The triennial user fee for enrolled agents and enrolled retirement plan agents is $140, or approximately $47 per year. Thus, the annualized cost of enrollment as an EA is approximately 0.0008 percent of the average yearly salary of an enrolled agent. The triennial user fee has increased from $67 to $140 per application for enrollment or renewal of enrollment. That amounts to a $73 increase per application for enrollment or renewal of enrollment. The increase amounts to $24.33 per year, or 0.0004 percent of the average yearly salary of an enrolled agent.

Based on the foregoing considerations, the Treasury Department and the IRS conclude that the rule is not expected to have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

After consideration of the comments, the proposed regulations are adopted without change.

Special Analyses

I. Regulatory Planning and Review

These regulations are not significant and are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the OMB regarding review of tax regulations.

II. Regulatory Flexibility Act

Pursuant to the RFA (5 U.S.C. chapter 6), it is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. As discussed in Section E of this preamble, the Treasury Department and the IRS have determined that the rule is not expected to have a significant economic impact

on a substantial number of small entities and a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking was submitted to the Chief Counsel of the Office of Advocacy of the SBA for comment on its impact on small business. The Chief Counsel for the Office of Advocacy of the SBA did not provide any written comments; however, they reached out to the Treasury Department and the IRS regarding comments they received from the NAEA.

III. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

IV. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These final regulations do not have federalism implications and do not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Drafting Information

The principal author of these regulations is Mark Shurtliff, Office of the Associate Chief Counsel (Procedure and Administration). Other personnel from the Treasury Department and the IRS participated in the development of the regulations.

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR part 300 as follows:

PART 300—USER FEES

■ **Paragraph. 1.** The authority citation for part 300 continues to read as follows:

Authority: 31 U.S.C. 9701.

■ **Par. 2.** Section 300.5 is amended by revising paragraphs (b) and (d) to read as follows:

§ 300.5 Enrollment of enrolled agent fee.

* * * * *

(b) *Fee.* The fee for initially enrolling as an enrolled agent with the IRS is $140.

* * * * *

(d) *Applicability date.* This section is applicable beginning October 31, 2022.

■ **Par. 3.** Section 300.6 is amended by revising paragraphs (b) and (d) to read as follows:

§ 300.6 Renewal of enrollment of enrolled agent fee.

* * * * *

(b) *Fee.* The fee for renewal of enrollment as an enrolled agent with the IRS is $140.

* * * * *

(d) *Applicability date.* This section is applicable beginning October 31, 2022.

■ **Par. 4.** Section 300.9 is amended by revising paragraphs (b) and (d) to read as follows:

§ 300.9 Renewal of enrollment of enrolled retirement plan agent fee.

* * * * *

(b) *Fee.* The fee for renewal of enrollment as an enrolled retirement plan agent with the IRS is $140.

* * * * *

(d) *Applicability date.* This section is applicable beginning October 31, 2022.

Paul J. Mamo,

Assistant Deputy Commissioner for Services and Enforcement.

Approved: September 20, 2022.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2022–21087 Filed 9–27–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 553

Central African Republic Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending the Central African Republic Sanctions Regulations and reissuing them in their entirety as a more comprehensive set of regulations that includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. This final rule replaces the regulations that were published in abbreviated form on July 7, 2014.

DATES: This rule is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On July 7, 2014, OFAC issued the Central African Republic Sanctions Regulations, 31 CFR part 553 (79 FR 38248, July 7, 2014) (the ''Regulations''), to implement Executive Order (E.O.) 13667 of May 12, 2014, ''Blocking Property of Certain Persons Contributing to the Conflict in the Central African Republic'' (79 FR 28387, May 15, 2014), pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13667. The Regulations were initially issued in abbreviated form for the purpose of providing immediate guidance to the public. OFAC is amending and reissuing the Regulations as a more comprehensive set of regulations that includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Regulations in their entirety.

On May 12, 2014, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA) and the United Nations Participation Act (22 U.S.C. 287c) (UNPA), issued E.O. 13667, effective at 12:01 a.m. eastern daylight time on May 13, 2014. In E.O. 13667, the President determined that the situation in and in relation to the Central African Republic, which has been marked by a breakdown of law and order, intersectarian tension, widespread violence and atrocities, and the pervasive, often forced recruitment and use of child soldiers, which threatens the peace, security, or stability of the Central African Republic and neighboring states, and which was addressed by the United Nations Security Council in Resolution 2121 of October 10, 2013, Resolution 2127 of December 5, 2013, and Resolution 2134 of January 28, 2014, constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States, and declared a national emergency to deal with that threat.

Section 1(a) of E.O. 13667 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of (i) the persons listed in the Annex to E.O. 13667; (ii) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State: (A) to be responsible for or complicit in, or to have engaged in, directly or indirectly, any of the following in or in relation to the Central African Republic: (1) actions or policies that threaten the peace, security, or stability of the Central African Republic; (2) actions or policies that threaten transitional agreements or the political transition process in the Central African Republic; (3) actions or policies that undermine democratic processes or institutions in the Central African Republic; (4) the targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law; (5) the use or recruitment of children by armed groups or armed forces in the context of the conflict in the Central African Republic; (6) the obstruction of the delivery or distribution of, or access to, humanitarian assistance; (7) attacks against United Nations missions, international security presences, or other peacekeeping operations; or (8) support to persons, including armed groups, involved in activities that threaten the peace, security, or stability of the Central African Republic or that undermine democratic processes or institutions in the Central African Republic through the illicit trade in natural resources of the Central African Republic; (B) except where intended for the authorized support of humanitarian activities or the authorized use by or support of peacekeeping, international, or government forces, to have directly or indirectly supplied, sold, or transferred to the Central African Republic, or been the recipient in the territory of the Central African Republic of, arms and related materiel, including military aircraft, and equipment, or advice, training, or assistance, including financing and financial assistance, related to military activities; (C) to be a leader of (i) an entity, including any armed group, that has, or whose members have, engaged in any of the activities described in subsections 1(a)(ii)(A) or (B) of E.O. 13667 or (ii) an entity whose property and interests in property are blocked pursuant to E.O. 13667; (D) to have materially assisted, sponsored, or provided financial, material, logistical, or technological support for, or goods or services in support of (i) any of the activities described in subsections 1(a)(ii)(A) or (B) of E.O. 13667 or (ii) any person whose property and interests in property are blocked pursuant to E.O. 13667; or (E) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to E.O. 13667.

The property and interests in property of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

In Section 2 of E.O. 13667, the President determined that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13667 would seriously impair the President's ability to deal with the national emergency declared in E.O. 13667. The President therefore prohibited the donation of such items except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to E.O 13667.

Section 3 of E.O. 13667 provides that the prohibition on any transaction or dealing in blocked property or interests in property includes the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13667, and the receipt of any contribution or provision of funds, goods, or services from any such person.

Section 5 of E.O. 13667 prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in E.O. 13667, as well as any conspiracy formed to violate such prohibitions.

Section 8 of E.O. 13667 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA and the UNPA, as may be necessary to carry out the purposes of E.O. 13667. Section 8 of E.O. 13667 also provides that the Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the U.S. government consistent with applicable law.

The Regulations implement targeted sanctions that are directed at persons determined to meet the criteria set forth in § 553.201 of the Regulations, as well as sanctions that may be set forth in any future Executive orders issued pursuant to the national emergency declared in E.O. 13667. The sanctions in E.O. 13667 do not generally prohibit trade or the provision of banking or other financial services to the Central African Republic. Instead, the sanctions in E.O. 13667 apply where the transaction or service in question involves property or interests in property that are blocked pursuant to these sanctions.

Subpart A of the Regulations clarifies the relation of this part to other laws and regulations. Subpart B of the Regulations implements the prohibitions contained in sections 1, 2, 3, and 5 of E.O. 13667, as well as the prohibitions contained in any further Executive orders issued pursuant to the national emergency declared in E.O. 13667. *See, e.g.,* §§ 553.201 and 553.205. Persons identified in the Annex to E.O. 13667, designated by or under the authority of the Secretary of the Treasury pursuant to E.O. 13667, or otherwise blocked pursuant to E.O. 13667, as well as persons who are blocked pursuant to any further Executive orders issued pursuant to the national emergency declared in E.O. 13667, are referred to throughout the

Regulations as ''persons whose property and interests in property are blocked pursuant to § 553.201.'' The names of persons listed in, or designated or identified as blocked pursuant to, E.O. 13667, or any further Executive orders issued pursuant to the national emergency declared therein, are published on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List), which is accessible via OFAC's website. Those names also are published in the **Federal Register** as they are added to the SDN List.

Sections 553.202 and 553.203 of subpart B detail the effect of transfers of blocked property in violation of the Regulations and set forth the requirement to hold blocked funds, such as currency, bank deposits, or liquidated financial obligations, in interest-bearing blocked accounts. Section 553.204 of subpart B provides that all expenses incident to the maintenance of blocked tangible property shall be the responsibility of the owners and operators of such property, and that such expenses shall not be met from blocked funds, unless otherwise authorized. The section further provides that blocked property may, in OFAC's discretion, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Section 553.205 of subpart B prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in § 553.201 of the Regulations, and any conspiracy formed to violate such prohibitions.

Section 553.206 of subpart B states transactions that are exempt from the prohibitions of the Regulations pursuant to section 203(b) of IEEPA (50 U.S.C. 1702(b)). As further set forth in this section, these exemptions do not apply to transactions involving persons whose property and interests in property are blocked under § 553.201 pursuant to the authority of the UNPA.

In subpart C of the Regulations, new definitions are being added to other key terms used throughout the Regulations. Because these new definitions were inserted in alphabetical order, the definitions that were in the prior abbreviated set of regulations have been renumbered. Similarly, in subpart D, which contains interpretive sections regarding the Regulations, certain provisions have been renumbered and others added to those in the prior abbreviated set of regulations.

Transactions otherwise prohibited by the Regulations but found to be consistent with U.S. policy may be authorized by one of the general licenses contained in subpart E of the Regulations or by a specific license issued pursuant to the procedures described in subpart E of 31 CFR part 501. General licenses and statements of licensing policy relating to this part also may be available through the Central African Republic sanctions page on OFAC's website: *www.treas.gov/ofac.*

Subpart F of the Regulations refers to subpart C of part 501 for recordkeeping and reporting requirements. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty or issuance of a Finding of Violation. Subpart G also refers to appendix A of part 501 for a more complete description of these procedures.

Subpart H of the Regulations refers to subpart E of part 501 for applicable provisions relating to administrative procedures and contains a delegation of certain authorities of the Secretary of the Treasury. Subpart I of the Regulations sets forth a Paperwork Reduction Act notice.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. 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 control number.

List of Subjects in 31 CFR Part 553

Administrative practice and procedure, Banks, banking, Blocking of assets, Central African Republic, Credit, Foreign trade, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

■ For the reasons set forth in the preamble, OFAC revises 31 CFR part 553 to read as follows:

PART 553—CENTRAL AFRICAN REPUBLIC SANCTIONS REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Subpart B—Prohibitions

Subpart C—General Definitions

Subpart D—Interpretations

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13667, 79 FR 28387, 3 CFR, 2014 Comp., p. 243.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 553.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Subpart B—Prohibitions

§ 553.201 Prohibited transactions.

(a) All property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(1) The persons listed in the Annex to E.O. 13667 of May 12, 2014; and

(2) Any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be responsible for or complicit in, or to have engaged in, directly or indirectly, any of the following in or in relation to the Central African Republic:

(A) Actions or policies that threaten the peace, security, or stability of the Central African Republic;

(B) Actions or policies that threaten transitional agreements or the political transition process in the Central African Republic;

(C) Actions or policies that undermine democratic processes or institutions in the Central African Republic;

(D) The targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law;

(E) The use or recruitment of children by armed groups or armed forces in the context of the conflict in the Central African Republic;

(F) The obstruction of the delivery or distribution of, or access to, humanitarian assistance;

(G) Attacks against United Nations missions, international security presences, or other peacekeeping operations; or

(H) Support to persons, including armed groups, involved in activities that threaten the peace, security, or stability of the Central African Republic or that undermine democratic processes or institutions in the Central African Republic through the illicit trade in natural resources of the Central African Republic;

(ii) Except where intended for the authorized support of humanitarian activities or the authorized use by or support of peacekeeping, international, or government forces, to have directly or indirectly supplied, sold, or transferred to the Central African Republic, or been the recipient in the territory of the Central African Republic of, arms and related materiel, including military aircraft, and equipment, or advice, training, or assistance, including financing and financial assistance, related to military activities;

(iii) To be a leader of:

(A) An entity, including any armed group, that has, or whose members have, engaged in any of the activities described in paragraph (a)(2)(i) or (ii) of this section; or

(B) An entity whose property and interests in property are blocked pursuant to paragraph (a) of this section;

(iv) To have materially assisted, sponsored, or provided financial, material, logistical, or technological support for, or goods or services in support of:

(A) Any of the activities described in paragraph (a)(2)(i) or (ii) of this section; or

(B) Any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; or

(v) To be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

(b) The prohibitions in paragraph (a) of this section include prohibitions on the following transactions:

(1) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; and

(2) The receipt of any contribution or provision of funds, goods, or services from any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

(c) Unless authorized by this part or by a specific license expressly referring to this part, any dealing in securities (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of, or known to be held for the benefit of, or issued by, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section is prohibited. This prohibition includes the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of, or the endorsement or guaranty of signatures on, any securities on or after the

effective date. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such securities may have or might appear to have assigned, transferred, or otherwise disposed of the securities.

(d) The prohibitions in paragraph (a) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

(e) All transactions prohibited pursuant to any Executive order issued after May 13, 2014 pursuant to the national emergency declared in E.O. 13667 of May 12, 2014 are prohibited pursuant to this part.

Note 1 to § 553.201. The names of persons designated or identified as blocked pursuant to E.O. 13667, or any further Executive orders issued pursuant to the national emergency declared therein, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) using the following identifiers: for E.O. 13667: ''[CAR]''; for any further Executive orders issued pursuant to the national emergency declared in E.O. 13667: using the identifier formulation ''[CAR–E.O.[E.O. number pursuant to which the person's property and interests in property are blocked]].'' The SDN List is accessible through the following page on OFAC's website: *www.treas.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. *See* § 553.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 553.201. The International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into the SDN List using the following identifiers: for E.O. 13667: ''[BPI–CAR]''; for any further Executive orders issued pursuant to the national emergency declared in E.O. 13667: ''[BPI–CAR–E.O.[E.O. number pursuant to which the person's property and interests in property are blocked pending investigation]].''

Note 3 to § 553.201. Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 553.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 553.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interest in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 553.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of this part and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

(e) The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(f) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property or interest in property blocked pursuant to § 553.201.

§ 553.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 553.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For the purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For the purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For the purposes of this section, if interest is credited to a separate blocked

account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 553.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 553.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as real or personal property, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds blocked pursuant to § 553.201 may not be held, invested, or reinvested in a manner that provides financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 553.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 553.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 553.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 553.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

§ 553.205 Evasions; attempts; causing violations; conspiracies.

(a) Any transaction on or after the effective date that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

§ 553.206 Exempt transactions.

(a) *United Nations Participation Act.* The exemptions cited in this section do not apply to transactions involving property or interests in property of persons whose property and interests in property are blocked pursuant to the authority of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA).

Note 1 to paragraph (a). Persons whose property and interests in property are blocked pursuant to the authority of the UNPA include those listed on *both* OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) and the Consolidated United Nations Security Council Sanctions List (UN List) (*see https://www.un.org*), as well as persons listed on the SDN List for being owned or controlled by, or acting for or on behalf of, persons listed on *both* the SDN List and the UN List.

(b) *International Emergency Economic Powers Act.* The prohibitions contained in this part do not apply to any transactions that are exempt pursuant to section 203(b) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)).

Subpart C—General Definitions

§ 553.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 553.301 Arms and related materiel.

The term *arms and related materiel* means arms or related materiel of all types, including military aircraft and equipment, transferred in contravention of the United Nations arms embargo on the Central African Republic.

§ 553.302 Blocked account; blocked property.

The terms *blocked account* and *blocked property* mean any account or property subject to the prohibitions in § 553.201 held in the name of a person whose property and interests in property are blocked pursuant to § 553.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 553.302. *See* § 553.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 553.201.

§ 553.303 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(1) With respect to a person whose property and interests in property are blocked pursuant to § 533.201(a)(1), 12:01 a.m. eastern daylight time, May 13, 2014; and

(2) With respect to a person whose property and interests in property are otherwise blocked pursuant to § 553.201, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, *constructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

§ 553.304 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 553.305 Financial, material, logistical, or technological support.

The term *financial, material, logistical, or technological support,* as used in this part, means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods. ''Technologies'' as used in this section means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 553.306 [Reserved]

§ 553.307 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* ''an interest in property''), means an interest of any nature whatsoever, direct or indirect.

§ 553.308 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's website: *www.treas.gov/ofac.*

(c) The term *specific license* means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC's website: *www.treas.gov/ofac.*

Note 1 to § 553.308. *See* § 501.801 of this chapter on licensing procedures.

§ 553.309 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

§ 553.310 Person.

The term *person* means an individual or entity.

§ 553.311 Property; property interest.

The terms *property* and *property interest* include money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership, or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 553.312 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 553.313 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 553.314 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 553.315 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, purchasing or selling foreign exchange, securities, futures, or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, money services businesses, operators of credit card systems, trust companies, insurance companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

Subpart D—Interpretations

§ 553.401 Reference to amended sections.

(a) Reference to any section in this part is a reference to the same as currently amended, unless the reference includes a specific date. *See* 44 U.S.C. 1510.

(b) Reference to any ruling, order, instruction, direction, or license issued pursuant to this part is a reference to the same as currently amended unless otherwise so specified.

§ 553.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 553.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 553.201, such property shall no longer be deemed to be property blocked pursuant to § 553.201, unless there exists in the property another interest that is blocked pursuant to § 553.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 553.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 553.404 Transactions ordinarily incident to a licensed transaction.

(a) Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(1) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 553.201; or

(2) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

(b) For example, a license authorizing a person to complete a securities sale involving Company A, whose property and interests in property are blocked pursuant to § 553.201, also authorizes other persons to engage in activities that are ordinarily incident and necessary to complete the sale, including transactions by the buyer, broker, transfer agents, and banks, provided that such other persons are not themselves persons whose property and interests in property are blocked pursuant to § 553.201.

§ 553.405 Provision and receipt of services.

(a) The prohibitions contained in § 553.201 apply to services performed in the United States or by U.S. persons, wherever located:

(1) On behalf of or for the benefit of any person whose property and interests in property are blocked pursuant to § 553.201; or

(2) With respect to property interests of any person whose property and interests in property are blocked pursuant to § 553.201.

(b) The prohibitions on transactions contained in § 553.201 apply to services received in the United States or by U.S. persons, wherever located, where the service is performed by, or at the direction of, a person whose property and interests in property are blocked pursuant to § 553.201.

(c) For example, U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting, financial, brokering, freight forwarding, transportation, public relations, or other services to any person whose property and interests in property are blocked pursuant to § 553.201, or negotiate with or enter into contracts signed by a person whose property and interests in property are blocked pursuant to § 553.201.

Note 1 to § 553.405. *See* §§ 553.507 and 553.509 for general licenses authorizing the provision of certain legal and emergency medical services.

§ 553.406 Offshore transactions involving blocked property.

The prohibitions in § 553.201 on transactions or dealings involving blocked property, as defined in § 553.302, apply to transactions by any U.S. person in a location outside the United States.

§ 553.407 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to § 553.201, no debits may be made to a blocked account to pay obligations to U.S. persons or other persons, except as authorized by or pursuant to this part.

Note 1 to § 553.407. *See also* § 553.502(e), which provides that no license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

§ 553.408 Charitable contributions.

Unless specifically authorized by OFAC pursuant to this part, no charitable contribution of funds, goods, services, or technology, including contributions to relieve human suffering, such as food, clothing, or medicine, may be made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 553.201. For the purposes of this part, a contribution is made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 553.201 if made by, to, or in the name of, or received from or in the name of, such a person; if made by, to, or in the name of, or received from or in the name of, an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade, or to avoid the bar on the provision of contributions by, to, or for the benefit of such a person, or the receipt of contributions from such a person.

§ 553.409 Credit extended and cards issued by financial institutions to a person whose property and interests in property are blocked.

The prohibition in § 553.201 on dealing in property subject to that section prohibits U.S. financial institutions from performing under any existing credit agreements, including charge cards, debit cards, or other credit facilities issued by a financial institution to a person whose property and interests in property are blocked pursuant to § 553.201.

§ 553.410 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. financial institution or other U.S. person, is a prohibited transfer under § 553.201 if effected after the effective date.

§ 553.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 553.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 553.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 553.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Central African Republic sanctions page on OFAC's website: *www.treas.gov/ofac.*

§ 553.502 Effect of license or other authorization.

(a) No license or other authorization contained in this part, or otherwise issued by OFAC, authorizes or validates any transaction effected prior to the issuance of such license or other authorization, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction, or license is issued by OFAC and specifically refers to this part. No regulation, ruling, instruction, or license referring to this part shall be deemed to authorize any transaction prohibited by any other part of this chapter unless the regulation,

ruling, instruction, or license specifically refers to such part.

(c) Any regulation, ruling, instruction, or license authorizing any transaction prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent specifically stated by its terms. Unless the regulation, ruling, instruction, or license otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(d) Nothing contained in this part shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain a license or other authorization from another department or agency of the U.S. government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency. For example, exports of goods, services, or technical data that are not prohibited by this part or that do not require a license by OFAC nevertheless may require authorization by the U.S. Department of Commerce, the U.S. Department of State, or other agencies of the U.S. government.

(e) No license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

(f) Any payment relating to a transaction authorized in or pursuant to this part that is routed through the U.S. financial system should reference the relevant OFAC general or specific license authorizing the payment to avoid the blocking or rejection of the transfer.

§ 553.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 553.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 553.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note 1 to § 553.504. *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 553.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 553.505 Entries in certain accounts for normal service charges.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 553.506 Investment and reinvestment of certain funds.

Subject to the requirements of § 553.203, U.S. financial institutions are authorized to invest and reinvest assets blocked pursuant to § 553.201, subject to the following conditions:

(a) The assets representing such investments and reinvestments are credited to a blocked account or subaccount that is held in the same name at the same U.S. financial institution, or within the possession or control of a U.S. person, but funds shall not be transferred outside the United States for this purpose;

(b) The proceeds of such investments and reinvestments shall not be credited to a blocked account or subaccount under any name or designation that differs from the name or designation of the specific blocked account or subaccount in which such funds or securities were held; and

(c) No immediate financial or economic benefit accrues (*e.g.,* through pledging or other use) to a person whose property and interests in property are blocked pursuant to § 553.201.

§ 553.507 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 553.201 is authorized, provided that any receipt of payment of professional fees and reimbursement of incurred expenses must be authorized pursuant to § 553.508, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 553.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by paragraph (a) of this section. Additionally, U.S. persons who provide services authorized by paragraph (a) of this section do not need to obtain specific authorization to contract for related services that are ordinarily

incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. *See* § 553.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 553.201 is prohibited unless licensed pursuant to this part.

Note 1 to § 553.507. Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available.

§ 553.508 Payments for legal services from funds originating outside the United States.

(a) *Professional fees and incurred expenses.* (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 553.507(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 553.201, is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person; or

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 553.507(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 553.201, any other part of this chapter, or any Executive order or statute has an interest.

(b) *Reports.* (1) U.S. persons who receive payments pursuant to paragraph (a) of this section must submit annual reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be submitted to OFAC using one of the following methods:

(i) *Email (preferred method): OFACReport@treasury.gov;* or

(ii) *U.S. Mail:* OFAC Regulations Reports, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Freedman's Bank Building, Washington, DC 20220.

§ 553.509 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are prohibited by this part are authorized.

§ 553.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

§ 553.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria and the Global Alliance for Vaccines and Immunizations.

Subpart F—Reports

§ 553.601 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart G—Penalties and Findings of Violation

§ 553.701 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to violations of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any license, order, regulation, or prohibition issued under IEEPA.

(2) IEEPA provides for a maximum civil penalty not to exceed the greater of $330,947 or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(3) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any license, order, regulation, or prohibition may, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b)(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially

false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(d) Section 5(b) of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA), provides that any person who willfully violates or evades or attempts to violate or evade any order, rule, or regulation issued by the President pursuant to Section 5(a) of the UNPA shall, upon conviction, be fined not more than $1,000,000 or, if a natural person, be imprisoned for not more than 20 years, or both.

(e) Violations involving transactions described at section 203(b)(1), (3), and (4) of IEEPA shall be subject only to the penalties set forth in paragraph (d) of this section.

(f) Violations of this part may also be subject to other applicable laws.

§ 553.702 Pre-Penalty Notice; settlement.

(a) *When required.* If OFAC has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) or the United Nations Participation Act (22 U.S.C. 287c) and determines that a civil monetary penalty is warranted, OFAC will issue a Pre-Penalty Notice informing the alleged violator of the agency's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing. The Pre-Penalty Notice may be issued whether or not another agency has taken any action with respect to the matter. For a description of the contents of a Pre-Penalty Notice, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to respond to a Pre-Penalty Notice by making a written presentation to OFAC. For a description of the information that should be included in such a response, see appendix A to part 501 of this chapter.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the Pre-Penalty Notice was mailed or date the Pre-Penalty Notice was emailed. If the Pre-Penalty Notice was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to a Pre-Penalty Notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the Pre-Penalty Notice, and include the OFAC identification number listed on the Pre-Penalty Notice. The response must be sent to OFAC's Office of Compliance and Enforcement by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(c) *Settlement.* Settlement discussion may be initiated by OFAC, the alleged violator, or the alleged violator's authorized representative. For a description of practices with respect to settlement, see appendix A to part 501 of this chapter.

(d) *Guidelines.* Guidelines for the imposition or settlement of civil penalties by OFAC are contained in appendix A to part 501 of this chapter.

(e) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific allegations contained in the Pre-Penalty Notice must be preceded by a written letter of representation, unless the Pre-Penalty Notice was served upon the alleged violator in care of the representative.

§ 553.703 Penalty imposition.

If, after considering any written response to the Pre-Penalty Notice and any relevant facts, OFAC determines that there was a violation by the alleged violator named in the Pre-Penalty Notice and that a civil monetary penalty is appropriate, OFAC may issue a Penalty Notice to the violator containing a determination of the violation and the imposition of the monetary penalty. For additional details concerning issuance of a Penalty Notice, see appendix A to part 501 of this chapter. The issuance of the Penalty Notice shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

§ 553.704 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to OFAC, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

§ 553.705 Findings of Violation.

(a) *When issued.* (1) OFAC may issue an initial Finding of Violation that identifies a violation if OFAC:

(i) Determines that there has occurred a violation of any provision of this part, or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) or the United Nations Participation Act (22 U.S.C. 287c);

(ii) Considers it important to document the occurrence of a violation; and

(iii) Based on the Guidelines contained in appendix A to part 501 of this chapter, concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial Finding of Violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter. For additional details concerning issuance of a Finding of Violation, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to contest an initial Finding of Violation by providing a written response to OFAC.

(2) *Deadline for response; Default determination.* A response to an initial Finding of Violation must be made

within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(i) *Computation of time for response.* A response to an initial Finding of Violation must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the initial Finding of Violation was served or date the Finding of Violation was sent by email. If the initial Finding of Violation was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to an initial Finding of Violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the initial Finding of Violation, and include the OFAC identification number listed on the initial Finding of Violation. The response must be sent to OFAC's Office of Compliance and Enforcement by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the regulations did not occur and/or why a Finding of Violation is otherwise unwarranted under the circumstances, with reference to the General Factors Affecting Administrative Action set forth in the Guidelines contained in appendix A to part 501 of this chapter. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a Finding of Violation is warranted.* If, after considering the response, OFAC determines that a final Finding of Violation should be issued, OFAC will issue a final Finding of Violation that will inform the violator of its decision. A final Finding of Violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(2) *Determination that a Finding of Violation is not warranted.* If, after considering the response, OFAC determines a Finding of Violation is not warranted, then OFAC will inform the alleged violator of its decision not to issue a final Finding of Violation.

Note: Note 1 to paragraph (c)(2).

A determination by OFAC that a final Finding of Violation is not warranted does not preclude OFAC from pursuing other enforcement actions consistent with the Guidelines contained in appendix A to part 501 of this chapter.

(d) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific alleged violations contained in the initial Finding of Violation must be preceded by a written letter of representation, unless the initial Finding of Violation was served upon the alleged violator in care of the representative.

Subpart H—Procedures

§ 553.801 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 553.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to E.O. 13667 of May 12, 2014 and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 553.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 588

Western Balkans Stabilization Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Western Balkans Stabilization Regulations and reissuing them in their entirety to further implement a June 26, 2001 Executive order and a May 28, 2003 Executive order related to the Western Balkans, and to implement a June 8, 2021 Western Balkans-related Executive order. This final rule replaces the regulations that were amended and reissued on June 29, 2011, and includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Western Balkans Stabilization Regulations in their entirety.

DATES: This rule is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On May 30, 2002, OFAC issued the Western Balkans Stabilization Regulations, 31 CFR part 588 (67 FR 37671, May 30, 2002) (the ''Regulations''), to implement Executive Order (E.O.) 13219 of June 26, 2001, ''Blocking Property of Persons Who Threaten International Stabilization Efforts in the Western Balkans'' (66 FR 34777, June 29, 2001), pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13219. On June 29, 2011, OFAC amended and reissued the Regulations (76 FR 38002, June 29, 2011) to implement E.O. 13304 of May 28, 2003, ''Termination of Emergencies With Respect to Yugoslavia and Modification of Executive Order 13219 of June 26, 2001'' (68 FR 32315, May 29, 2003), which amended E.O. 13219 (''amended E.O. 13219''), pursuant to authorities delegated to the Secretary of the Treasury. OFAC is revising the Regulations to further implement amended E.O. 13219 and to implement E.O. 14033 of June 8, 2021, ''Blocking Property and Suspending Entry Into the United States of Certain Persons Contributing to the Destabilizing Situation in the Western Balkans'' (86 FR 31079, June 10, 2021). Due to the number of regulatory sections being updated or added, OFAC is reissuing the Regulations in their entirety.

E.O. 13219

On June 26, 2001, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), issued E.O. 13219. In E.O. 13219, the President determined that the actions of persons engaged in, or assisting, sponsoring, or supporting, (i) extremist violence in the former Yugoslav Republic of Macedonia, southern Serbia, the Federal Republic of Yugoslavia, and elsewhere in the Western Balkans region, or (ii) acts obstructing implementation of the Dayton Accords in Bosnia or United Nations Security Council Resolution (UNSCR) 1244 of June 10, 1999, in Kosovo, constitute an unusual and extraordinary threat to the national security and foreign policy of the United States and declared a national emergency to deal with that threat. E.O. 13219 blocked the property and interests in property of certain persons, including the persons listed in the Annex to E.O. 13219. *See* 66 FR 34777 (June 29, 2001).

E.O. 13304

On May 28, 2003, the President, pursuant to, *inter alia,* IEEPA, and the United Nations Participation Act, as amended (22 U.S.C. 287c) (UNPA), issued E.O. 13304. In E.O. 13304, the President took additional steps with respect to continuing, widespread, and illicit actions obstructing implementation of the Ohrid Framework Agreement of 2001, relating to Macedonia, UNSCR 1244 of June 10, 1999, relating to Kosovo, or the Dayton Accords or the Conclusions of the Peace Implementation Conference Council held in London on December 8–9, 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council or its Steering Board, relating to Bosnia and Herzegovina, including the harboring of individuals indicted by the International Criminal Tribunal for the former Yugoslavia, and with respect to the national emergency described and declared in E.O. 13219. E.O. 13304 amended E.O. 13219 to expand and clarify the scope of persons targeted by the blocking sanctions. *See* 76 FR 38002 (June 29, 2011).

E.O. 14033

On June 8, 2021, pursuant to, *inter alia,* IEEPA, the President issued E.O. 14033. In E.O. 14033, the President expanded the scope of the national emergency declared in E.O. 13219, as amended in E.O. 13304, finding that the situation in the territory of the former Socialist Federal Republic of Yugoslavia and the Republic of Albania (the Western Balkans), over the past two decades, including the undermining of post-war agreements and institutions following the breakup of the former Socialist Federal Republic of Yugoslavia, as well as widespread corruption within various governments and institutions in the Western Balkans, stymies progress toward effective and democratic governance and full integration into transatlantic institutions, and thereby constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States.

Section 1(a) of E.O. 14033 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of any person determined by the Secretary of the Treasury, in consultation with the Secretary of State: (i) to be responsible for or complicit in, or to have directly or indirectly engaged in, actions or policies that threaten the peace, security, stability, or territorial integrity of any area or state in the Western Balkans; (ii) to be responsible for or complicit in, or to have directly or indirectly engaged in, actions or policies that undermine democratic processes or institutions in the Western Balkans; (iii) to be responsible for or complicit in, or to have directly or indirectly engaged in, a violation of, or an act that has obstructed or threatened the implementation of, any regional security, peace, cooperation, or mutual recognition agreement or framework or accountability mechanism related to the Western Balkans, including the Prespa Agreement of 2018; the Ohrid Framework Agreement of 2001; UNSCR 1244; the Dayton Accords; or the Conclusions of the Peace Implementation Conference Council held in London in December 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council, or its Steering Board; or the International Criminal Tribunal for the former Yugoslavia, or, with respect to the former Yugoslavia, the International Residual Mechanism for Criminal Tribunals; (iv) to be responsible for or complicit in, or to have directly or indirectly engaged in, serious human rights abuse in the Western Balkans; (v) to be responsible for or complicit in, or to have directly or indirectly engaged in, corruption related to the Western Balkans, including corruption by, on behalf of, or otherwise related to a government in the Western Balkans, or a current or former government official at any level of government in the Western Balkans, such as the misappropriation of public assets, expropriation of private assets for personal gain or political purposes, or bribery; (vi) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any person whose property and interests in property are blocked pursuant to this order; or (vii) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to E.O. 14033.

Section 2 of E.O. 14033 provides that the prohibition on any transaction or dealing in blocked property or interests in property includes the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 14033, and the receipt

of any contribution or provision of funds, goods, or services from any such person.

In Section 3 of E.O. 14033, the President determined that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)), by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 14033 would seriously impair the President's ability to deal with the national emergency declared in E.O. 13219 as expanded in E.O. 14033. The President therefore prohibited the donation of such items except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to E.O. 14033.

Section 5 of E.O. 14033 prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in E.O. 14033, as well as any conspiracy formed to violate such prohibitions.

Section 8 of E.O. 14033 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA, as may be necessary to carry out the purposes of E.O. 14033. Section 8 of E.O. 14033 also provides that the Secretary of the Treasury may redelegate any of these functions within the Department of the Treasury.

Section 9 of E.O. 14033 exempts from the prohibitions of the order transactions for the conduct of the official business of the Federal Government by employees, grantees, or contractors thereof.

Current Regulatory Action

In furtherance of the purpose of amended E.O. 13219 and E.O. 14033, OFAC is reissuing the Regulations. The Regulations implement targeted sanctions that are directed at persons determined to meet the criteria set forth in § 588.201 of the Regulations, as well as sanctions that may be set forth in any future Executive orders issued pursuant to the national emergency declared in E.O. 13219 and expanded in E.O. 14033.

Subpart A of the Regulations clarifies the relation of this part to other laws and regulations. Subpart B of the Regulations implements the prohibitions contained in section 1(a) of amended E.O. 13219 and 1(a) of E.O. 14033, as well as the prohibitions contained in any further Executive orders issued pursuant to the national emergency declared in E.O. 13219. *See, e.g.,* §§ 588.201 and 588.205. Persons identified in the Annex to amended E.O. 13219 and persons otherwise blocked pursuant to amended E.O. 13219, E.O. 14033, or any further Executive order issued pursuant to the national emergency declared in E.O. 13219, are referred to throughout the Regulations as ''persons whose property and interests in property are blocked pursuant to § 588.201.''

Section 588.206 of subpart B states certain transactions that are exempt from the prohibitions of the Regulations pursuant to sections 203(b) of IEEPA (50 U.S.C. 1702(b)), or pursuant to section 9 of E.O. 14033, which relates to activities for the official business of the United States Government. As further set forth in this section, these exemptions do not apply to transactions involving persons whose property and interests in property are blocked pursuant to § 553.201 who are blocked pursuant to the authority of the UNPA in addition to IEEPA.

In subpart C of the Regulations, three new definitions are being added to other key terms used throughout the Regulations, one section that explains the applicability of the definitions in subpart C is being added, and certain updates are being made to existing definitions. The existing definitions are being renumbered so that subpart C is in alphabetical order.

In subpart D, which contains interpretive sections regarding the Regulations, certain provisions are being updated. Section 588.411 of subpart D explains that the property and interests in property of an entity are blocked if the entity is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked, whether the entity itself is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Transactions otherwise prohibited by the Regulations but found to be consistent with U.S. policy may be authorized by one of the general licenses contained in subpart E of the Regulations or by a specific license issued pursuant to the procedures described in subpart E of 31 CFR part 501. General licenses and statements of licensing policy relating to this part also may be available through the Balkans-related sanctions page on OFAC's website: *www.treas.gov/ofac.*

OFAC is also incorporating three new general licenses into the Regulations, renumbering existing general licenses, and making technical edits to certain existing general licenses. Section 588.508 was renumbered as § 588.509. In §§ 588.507 and 588.509, OFAC has removed the requirement that the receipt of payment for legal or emergency medical services be specifically licensed and made other updates. New §§ 588.508, 588.510, and 588.11 authorize, respectively, payments for legal services from funds originating outside the United States, official business of the United States Government, and official activities of certain international organizations and other international entities.

Subpart F of the Regulations refers to subpart C of part 501 for recordkeeping and reporting requirements. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty or issuance of a Finding of Violation. Subpart G also refers to appendix A of part 501 for a more complete description of these procedures.

Subpart H of the Regulations refers to subpart E of part 501 for applicable provisions relating to administrative procedures and contains a delegation of certain authorities of the Secretary of the Treasury. Subpart I of the Regulations sets forth a Paperwork Reduction Act notice.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. 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 control number.

List of Subjects in 31 CFR Part 588

Administrative practice and procedure, Banks, banking, Blocking of

assets, Credit, Foreign trade, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services, Western Balkans.

■ For the reasons set forth in the preamble, OFAC revises 31 CFR part 588 to read as follows:

PART 588—WESTERN BALKANS STABILIZATION REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Subpart B—Prohibitions

Subpart C—General Definitions

Subpart D—Interpretations

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

Subpart F—Reports

Subpart G—Penalties and Findings of Violation

Subpart H—Procedures

Subpart I—Paperwork Reduction Act

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13219, 66 FR 34777, 3 CFR, 2001 Comp., p. 778; E.O. 13304, 68 FR 32315, 3 CFR, 2004 Comp. p. 229; E.O. 14033, 86 FR 43905.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 588.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Subpart B—Prohibitions

§ 588.201 Prohibited transactions.

(a) All property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(1) *E.O. 13219 Annex.* The persons listed in the Annex to E.O. 13219 of June 26, 2001, as amended by E.O. 13304 of May 28, 2003; and

(2) *E.O. 13219 as amended by E.O. 13304.* Any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be under open indictment by the International Criminal Tribunal for the former Yugoslavia, unless circumstances warrant otherwise;

(ii) To have committed, or to pose a significant risk of committing, acts of violence that have the purpose or effect of threatening the peace in or diminishing the stability or security of any area or state in the Western Balkans region, undermining the authority, efforts, or objectives of international organizations or entities present in the region, or endangering the safety of persons participating in or providing support to the activities of those international organizations or entities;

(iii) To have actively obstructed, or pose a significant risk of actively obstructing, the Ohrid Framework Agreement of 2001 relating to Macedonia, UNSCR 1244 relating to Kosovo, or the Dayton Accords or the Conclusions of the Peace Implementation Conference held in London on December 8–9, 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council or its Steering Board, relating to Bosnia and Herzegovina;

(iv) To have materially assisted in, sponsored, or provided financial, material, or technological support for, or goods or services in support of, such acts of violence or obstructionism or any person listed in or designated pursuant to paragraph (a)(1) of this section or this paragraph (a)(2); or

(v) To be owned or controlled by, or acting or purporting to act directly or indirectly for or on behalf of, any person listed in or designated pursuant to paragraph (a)(1) of this section or this paragraph (a)(2).

(3) *E.O. 14033.* Any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be responsible for or complicit in, or to have directly or indirectly engaged in, actions or policies that threaten the peace, security, stability, or territorial integrity of any area or state in the Western Balkans;

(ii) To be responsible for or complicit in, or to have directly or indirectly engaged in, actions or policies that undermine democratic processes or institutions in the Western Balkans;

(iii) To be responsible for or complicit in, or to have directly or indirectly engaged in, a violation of, or an act that has obstructed or threatened the implementation of, any regional security, peace, cooperation, or mutual recognition agreement or framework or accountability mechanism related to the Western Balkans, including the Prespa Agreement of 2018; the Ohrid Framework Agreement of 2001; United Nations Security Council Resolution 1244; the Dayton Accords; or the Conclusions of the Peace Implementation Conference Council held in London in December 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council, or its Steering Board; or the International Criminal Tribunal for the former Yugoslavia, or, with respect to the former Yugoslavia, the International Residual Mechanism for Criminal Tribunals;

(iv) To be responsible for or complicit in, or to have directly or indirectly engaged in, serious human rights abuse in the Western Balkans;

(v) To be responsible for or complicit in, or to have directly or indirectly engaged in, corruption related to the Western Balkans, including corruption by, on behalf of, or otherwise related to a government in the Western Balkans, or a current or former government official at any level of government in the Western Balkans, such as the misappropriation of public assets, expropriation of private assets for personal gain or political purposes, or bribery;

(vi) To have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any person whose property and interests in property are blocked pursuant to paragraph this (a)(3); or

(vii) To be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this paragraph (a)(3).

(b) The prohibitions of this section include prohibitions on the following transactions:

(1) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this section; and

(2) The receipt of any contribution or provision of funds, goods, or services from any person whose property and interests in property are blocked pursuant to this section.

(c) Unless authorized by this part or by a specific license expressly referring to this part, any dealing in securities (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of, or known to be held for the benefit of, or issued by, any person whose property and interests in property are blocked pursuant to this section is prohibited. This prohibition includes the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of, or the endorsement or guaranty of signatures on, any securities on or after the effective date. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such securities may have or might appear to have assigned, transferred, or otherwise disposed of the securities.

(d) The prohibitions of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

(e) All transactions prohibited pursuant to any Executive order issued after June 8, 2021 pursuant to the national emergency declared in E.O. 13219 of June 27, 2001 are prohibited pursuant to this part.

Note 1 to § 588.201. The names of persons designated or identified as blocked pursuant to E.O. 13219; E.O. 13219, as amended by E.O. 13304 of May 28, 2003 (''amended E.O. 13219''); E.O. 14033; or any further Executive orders issued pursuant to the national emergency declared in E.O. 13219, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) using the following identifiers: for E.O. 13219 and amended E.O. 13219: ''BALKANS''; and for any further Executive orders issued pursuant to the national emergency declared in E.O. 13219: using the identifier formulation ''BALKANS–E.O.[E.O. number pursuant to which the person's property and interests in property are blocked].'' The SDN List is accessible through the following page on OFAC's website: *www.treasury.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. *See* § 588.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 588.201. The International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into the SDN List using the following identifiers: for E.O. 13219 or amended E.O. 13219: ''[BPI–BALKANS]''; for any further Executive orders issued pursuant to the national emergency declared in E.O. 13219: ''[BPI–BALKANS–EO[E.O. number pursuant to which the person's property and interests in property are blocked pending investigation]].''

Note 3 to § 588.201. Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 588.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 588.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interest in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 588.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it

would be valid or enforceable but for the provisions of this part and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

(e) The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(f) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property or interest in property blocked pursuant to § 588.201.

§ 588.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 588.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For the purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For the purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For the purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 588.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 588.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as real or personal property, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds blocked pursuant to § 588.201 may not be held, invested, or reinvested in a manner that provides financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 588.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 588.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 588.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 588.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

§ 588.205 Evasions; attempts; causing violations; conspiracies.

(a) Any transaction on or after the effective date that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

§ 588.206 Exempt transactions.

(a) *United Nations Participation Act.* The exemptions cited in this section do not apply to transactions involving property or interests in property of persons whose property and interests in property are blocked pursuant to the authority of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA).

Note 1 to paragraph (a). Persons whose property and interests in property are blocked pursuant to the authority of the UNPA include those listed on *both* OFAC's Specially Designated Nationals and Blocked Persons List and the Consolidated United Nations Security Council Sanctions List (*see https://www.un.org).*

(b) *International Emergency Economic Powers Act.* The prohibitions contained in this part do not apply to any transactions that are exempt pursuant to section 203(b) of the International

Emergency Economic Powers Act, (50 U.S.C. 1702(b)).

(c) *Official business.* The prohibitions contained in § 588.201(a)(3) do not apply to any transactions for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

Subpart C—General Definitions

§ 588.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 588.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* mean any account or property subject to the prohibitions in § 588.201 held in the name of a person whose property and interests in property are blocked pursuant to § 588.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 588.301. *See* § 588.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 588.201.

§ 588.302 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(1) With respect to a person whose property and interests in property are blocked pursuant to § 588.201(a)(1), whose name appeared on the Annex to E.O. 13219 as originally issued and also appeared on the Annex to E.O. 13304, 12:01 a.m. eastern daylight time June 27, 2001;

(2) With respect to a person whose property and interests in property are blocked pursuant to § 588.201(a)(1), whose name first appeared on the Annex to E.O. 13304, which replaced and superseded the Annex to E.O. 13219, 12:01 a.m. eastern daylight time May 29, 2003; and

(3) With respect to a person whose property and interests in property are otherwise blocked pursuant to § 588.201, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, c*onstructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

§ 588.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 588.304 Financial, material, or technological support.

The term *financial, material, or technological support,* as used in this part, means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods. ''Technologies'' as used in this section means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 588.305 [Reserved]

§ 588.306 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* ''an interest in property''), means an interest of any nature whatsoever, direct or indirect.

§ 588.307 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's website: *www.treas.gov/ofac.*

(c) The term *specific license* means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC's website: *www.treas.gov/ofac.*

Note 1 to § 588.306. *See* § 501.801 of this chapter on licensing procedures.

§ 588.308 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

§ 588.309 Person.

The term *person* means an individual or entity.

§ 588.310 Property; property interest.

The terms *property* and *property interest* include money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership, or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 588.311 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by

reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 588.312 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 588.313 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 588.314 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, money services businesses, trust companies, insurance companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

§ 588.315 Western Balkans.

The term *Western Balkans* means the territory of the former Socialist Federal Republic of Yugoslavia and the Republic of Albania.

Subpart D—Interpretations

§ 588.401 Reference to amended sections.

(a) Reference to any section in this part is a reference to the same as currently amended, unless the reference includes a specific date. *See* 44 U.S.C. 1510.

(b) Reference to any ruling, order, instruction, direction, or license issued pursuant to this part is a reference to the same as currently amended unless otherwise so specified.

§ 588.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 588.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 588.201, such property shall no longer be deemed to be property blocked pursuant to § 588.201, unless there exists in the property another interest that is blocked pursuant to § 588.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 588.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 588.404 Transactions ordinarily incident to a licensed transaction.

(a) Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(1) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 588.201; or

(2) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

(b) For example, a license authorizing a person to complete a securities sale involving Company A, whose property and interests in property are blocked pursuant to § 588.201, also authorizes other persons to engage in activities that are ordinarily incident and necessary to complete the sale, including transactions by the buyer, broker, transfer agents, and banks, provided that such other persons are not themselves persons whose property and interests in property are blocked pursuant to § 588.201.

§ 588.405 Provision and receipt of services.

(a) The prohibitions contained in § 588.201 apply to services performed in the United States or by U.S. persons, wherever located:

(1) On behalf of or for the benefit of any person whose property and interests in property are blocked pursuant to § 588.201; or

(2) With respect to property interests of any person whose property and interests in property are blocked pursuant to § 588.201.

(b) The prohibitions on transactions contained in § 588.201 apply to services received in the United States or by U.S. persons, wherever located, where the service is performed by, or at the direction of, a person whose property and interests in property are blocked pursuant to § 588.201.

(c) For example, U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting, financial, brokering, freight forwarding, transportation, public relations, or other services to any person whose property and interests in property are blocked pursuant to § 588.201, or negotiate with or enter into contracts signed by a person whose property and interests in property are blocked pursuant to § 588.201.

Note 1 to § 588.405. *See* §§ 588.5507 and 588.509 for general licenses authorizing the provision of certain legal and emergency medical services.

§ 588.406 Offshore transactions involving blocked property.

The prohibitions in § 588.201 on transactions or dealings involving blocked property, as defined in § 588.301, apply to transactions by any U.S. person in a location outside the United States.

§ 588.407 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to § 588.201, no debits may be made to a blocked account to pay obligations to U.S. persons or other

persons, except as authorized by or pursuant to this part.

Note 1 to § 588.407. *See also* § 588.502(e), which provides that no license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

§ 588.408 Charitable contributions.

Unless specifically authorized by OFAC pursuant to this part, no charitable contribution of funds, goods, services, or technology, including contributions to relieve human suffering, such as food, clothing, or medicine, may be made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 588.201. For the purposes of this part, a contribution is made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 588.201 if made by, to, or in the name of, or received from or in the name of, such a person; if made by, to, or in the name of, or received from or in the name of, an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade, or to avoid the bar on the provision of contributions by, to, or for the benefit of such a person, or the receipt of contributions from such a person.

§ 588.409 Credit extended and cards issued by financial institutions to a person whose property and interests in property are blocked.

The prohibition in § 588.201 on dealing in property subject to that section prohibits U.S. financial institutions from performing under any existing credit agreements, including charge cards, debit cards, or other credit facilities issued by a financial institution to a person whose property and interests in property are blocked pursuant to § 588.201.

§ 588.410 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. financial institution or other U.S. person, is a prohibited transfer under § 588.201 if effected after the effective date.

§ 588.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 588.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 588.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 588.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Balkans-Related sanctions page on OFAC's website: *www.treas.gov/ofac.*

§ 588.502 Effect of license or other authorization.

(a) No license or other authorization contained in this part, or otherwise issued by OFAC, authorizes or validates any transaction effected prior to the issuance of such license or other authorization, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction, or license is issued by OFAC and specifically refers to this part. No regulation, ruling, instruction, or license referring to this part shall be deemed to authorize any transaction prohibited by any other part of this chapter unless the regulation, ruling, instruction, or license specifically refers to such part.

(c) Any regulation, ruling, instruction, or license authorizing any transaction prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent specifically stated by its terms. Unless the regulation, ruling, instruction, or license otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(d) Nothing contained in this part shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain a license or other authorization from another department or agency of the U.S. Government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency. For example, exports of goods, services, or technical data that are not prohibited by this part or that do not require a license by OFAC nevertheless may require authorization by the U.S. Department of Commerce, the U.S. Department of State, or other agencies of the U.S. Government.

(e) No license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

(f) Any payment relating to a transaction authorized in or pursuant to this part that is routed through the U.S. financial system should reference the relevant OFAC general or specific license authorizing the payment to avoid the blocking or rejection of the transfer.

§ 588.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 588.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 588.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note 1 to § 588.504. *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 588.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 588.505 Entries in certain accounts for normal service charges.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 588.506 Investment and reinvestment of certain funds.

Subject to the requirements of § 588.203, U.S. financial institutions are authorized to invest and reinvest assets blocked pursuant to § 588.201, subject to the following conditions:

(a) The assets representing such investments and reinvestments are credited to a blocked account or subaccount that is held in the same name at the same U.S. financial institution, or within the possession or control of a U.S. person, but funds shall not be transferred outside the United States for this purpose;

(b) The proceeds of such investments and reinvestments shall not be credited to a blocked account or subaccount under any name or designation that differs from the name or designation of the specific blocked account or subaccount in which such funds or securities were held; and

(c) No immediate financial or economic benefit accrues (*e.g.,* through pledging or other use) to a person whose property and interests in property are blocked pursuant to § 588.201.

§ 588.507 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 588.201 is authorized, provided that any receipt of payment of professional fees and reimbursement of incurred expenses must be authorized pursuant to § 588.508, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 588.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by paragraph (a) of this section. Additionally, U.S. persons who provide services authorized by paragraph (a) of this section do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. *See* § 588.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 588.201 is prohibited unless licensed pursuant to this part.

Note 1 to § 588.507. Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available.

§ 588.508 Payments for legal services from funds originating outside the United States.

(a) *Professional fees and incurred expenses.* (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 588.507(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 588.201, is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person; or

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 588.507(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) of this section authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 588.201, any other part of this chapter, or any Executive order or statute has an interest.

(b) *Reports.* (1) U.S. persons who receive payments pursuant to paragraph (a) of this section must submit annual reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be submitted to

OFAC using one of the following methods:

(i) Email (preferred method): *OFACReport@treasury.gov;* or

(ii) U.S. mail: OFAC Regulations Reports, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, NW, Freedman's Bank Building, Washington, DC 20220.

§ 588.509 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are prohibited by this part are authorized.

§ 588.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

§ 588.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria and the Global Alliance for Vaccines and Immunizations.

Subpart F—Reports

§ 588.601 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart G—Penalties and Findings of Violation

§ 588.701 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to violations of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any license, order, regulation, or prohibition issued under IEEPA.

(2) IEEPA provides for a maximum civil penalty not to exceed the greater of $330,947 or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(3) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any license, order, regulation, or prohibition may, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b)(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(d) Section 5(b) of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA), provides that any person who willfully violates or evades or attempts to violate or evade any order, rule, or regulation issued by the President pursuant to Section 5(a) of the UNPA shall, upon conviction, be fined not more than $1,000,000 and, if a natural person, may also be imprisoned for not more than 20 years or both.

(e) Violations involving transactions described at section 203(b)(1) of IEEPA shall be subject only to the penalties set forth in paragraph (d) of this section.

(f) Violations of this part may also be subject to other applicable laws.

§ 588.702 Pre-Penalty Notice; settlement.

(a) *When required.* If OFAC has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and determines that a civil monetary penalty is warranted, OFAC will issue a Pre-Penalty Notice informing the alleged violator of the agency's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing. The Pre-Penalty Notice may be issued whether or not another agency has taken any action with respect to the matter. For a description of the contents of a Pre-Penalty Notice, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to respond to a Pre-Penalty Notice by making a written presentation to OFAC. For a description of the information that should be included in such a response, see appendix A to part 501 of this chapter.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the Pre-Penalty Notice was mailed or date the Pre-Penalty Notice was emailed. If the Pre-Penalty Notice was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or

weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to a Pre-Penalty Notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the Pre-Penalty Notice, and include the OFAC identification number listed on the Pre-Penalty Notice. The response must be sent to OFAC's Office of Compliance and Enforcement by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(c) *Settlement.* Settlement discussion may be initiated by OFAC, the alleged violator, or the alleged violator's authorized representative. For a description of practices with respect to settlement, see appendix A to part 501 of this chapter.

(d) *Guidelines.* Guidelines for the imposition or settlement of civil penalties by OFAC are contained in appendix A to part 501 of this chapter.

(e) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific allegations contained in the Pre-Penalty Notice must be preceded by a written letter of representation, unless the Pre-Penalty Notice was served upon the alleged violator in care of the representative.

§ 588.703 Penalty imposition.

If, after considering any written response to the Pre-Penalty Notice and any relevant facts, OFAC determines that there was a violation by the alleged violator named in the Pre-Penalty Notice and that a civil monetary penalty is appropriate, OFAC may issue a Penalty Notice to the violator containing a determination of the violation and the imposition of the monetary penalty. For additional details concerning issuance of a Penalty Notice, see appendix A to part 501 of this chapter. The issuance of the Penalty Notice shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

§ 588.704 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to OFAC, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

§ 588.705 Findings of Violation.

(a) *When issued.* (1) OFAC may issue an initial Finding of Violation that identifies a violation if OFAC:

(i) Determines that there has occurred a violation of any provision of this part, or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*);

(ii) Considers it important to document the occurrence of a violation; and

(iii) Based on the Guidelines contained in appendix A to part 501 of this chapter, concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial Finding of Violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter. For additional details concerning issuance of a Finding of Violation, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to contest an initial Finding of Violation by providing a written response to OFAC.

(2) *Deadline for response; Default determination.* A response to an initial Finding of Violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(i) *Computation of time for response.* A response to an initial Finding of Violation must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the initial Finding of Violation was served or date the Finding of Violation was sent by email. If the initial Finding of Violation was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to an initial Finding of Violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the initial Finding of Violation, and include the OFAC identification number listed on the initial Finding of Violation. The response must be sent to OFAC's Office of Compliance and Enforcement by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the regulations did not occur and/or why a Finding of Violation is otherwise unwarranted under the circumstances, with reference to the General Factors Affecting Administrative Action set forth in the Guidelines contained in appendix A to part 501 of this chapter. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a Finding of Violation is warranted.* If, after considering the response, OFAC determines that a final Finding of Violation should be issued, OFAC will issue a final Finding of Violation that will inform the violator of its decision. A final Finding of Violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(2) *Determination that a Finding of Violation is not warranted.* If, after considering the response, OFAC determines a Finding of Violation is not warranted, then OFAC will inform the alleged violator of its decision not to issue a final Finding of Violation.

Note 1 to paragraph (c)(2). A determination by OFAC that a final Finding of Violation is not warranted does not preclude OFAC from pursuing other enforcement actions consistent with the Guidelines contained in appendix A to part 501 of this chapter.

(d) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific alleged violations contained in the initial Finding of Violation must be preceded by a written letter of representation, unless the initial Finding of Violation was served upon the alleged violator in care of the representative.

Subpart H—Procedures

§ 588.801 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 588.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to E.O. 13219 of June 26, 2001, as amended by E.O. 13304 of May 28, 2003, E.O. 14033 of June 8, 2021, and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 588.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–20992 Filed 9–28–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0691]

Regulated Area; San Francisco Bay Navy Fleet Week Parade of Ships and Blue Angels Demonstration, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the limited access area in the navigable waters of the San Francisco Bay for the San Francisco Bay Navy Fleet Week Parade of Ships and Blue Angels Survey Flight and Demonstration days from October 6 through October 9, 2022. This action is necessary to ensure the safety of event participants and spectators. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the regulated area, unless authorized by the Patrol Commander (PATCOM). This notification of enforcement (NOE) announces new dates and times for enforcement and supersedes the previous NOE published for this event.

DATES: The regulations in 33 CFR 100.1105 will be enforced from 12:30 p.m. until 6 p.m. on October 6, 2022; from 9:30 a.m. until 5 p.m. on October 7, 2022; and from 11:30 a.m. until 5 p.m. daily on October 8, 2022 and October 9, 2022, as identified in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony Solares, Coast Guard Sector San Francisco, Waterways Management Division, 415–399–3585, *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the limited access area for the annual San Francisco Bay Navy Fleet Week Parade of Ships and Blue Angels Demonstration in 33 CFR 100.1105. This NOE supersedes the NOE published on September 6, 2022 at 87 FR 54390 for the same annual San Francisco Bay Navy Fleet Week Parade of Ships and Blue Angels Demonstration. A copy of the published NOE is also available in the docket USCG–2022–0691 on *regulations.gov*. After publication of that NOE, the event sponsor notified the Coast Guard that they needed to adjust the times of the event. This NOE announces the updated dates and times this limited access area will be enforced daily on October 6th through October 9th, 2022 as described in the following paragraph.

The regulated area ''Alpha'' in § 100.1105(b)(1) for the Navy Parade of Ships will be enforced from 9:30 a.m. until 12 p.m. on October 7, 2022. The regulated area ''Bravo'' in § 100.1105(b)(2) for the U.S. Navy Blue Angels will be enforced from 12:30 p.m. until 6 p.m. on October 6, 2022, and 11:30 a.m. until 5 p.m. daily from October 7, 2022 through October 9, 2022.

Regulated area ''Alpha'' will be enforced during the Navy Parade of Ships and is bounded by a line connecting the following points and thence along the shore to the point of beginning:

Latitude	Longitude
37°48′40″ N	122°28′38″ W
37°49′10″ N	122°28′41″ W
37°49′31″ N	122°25′18″ W
37°49′06″ N	122°24′08″ W
37°47′53″ N	122°22′42″ W
37°46′00″ N	122°22′00″ W
37°46′00″ N	122°23′07″ W

Under the provisions of 33 CFR 100.1105, except for persons or vessels authorized by the PATCOM, in regulated area ''Alpha'' no person or vessel may enter the parade route or remain within 500 yards of any Navy parade vessel. No person or vessel shall anchor, block, loiter in, or impede the through transit of ship parade participants or official patrol vessels in regulated area ''Alpha.''

Regulated area ''Bravo'' will be enforced during the Navy Blue Angels Demonstration and is bounded by a line connecting the following points and thence along the pierheads and bulwarks to the point of beginning:

Latitude	Longitude
37°48′27.5″ N	122°24′04″ W
37°49′31″ N	122°24′18″ W
37°49′00″ N	122°27′52″ W
37°48′19″ N	122°27′40″ W

Except for persons or vessels authorized by the PATCOM, no person or vessel may enter or remain within regulated area ''Bravo.''

When hailed or signaled by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, a person or vessel shall come to an immediate stop. Persons or vessels shall comply with all directions given; failure to do so may result in expulsion from the area, citation for failure to comply, or

both. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco, California. The PATCOM is empowered to forbid and control the movement of all vessels in the regulated areas.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners.

Dated: September 23, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2022–21099 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0794]

Safety Zone; Monte Foundation Fireworks, Capitola Pier, Capitola, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Monte Foundation Fireworks Display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM) or other federal, state, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulations in 33 CFR 165.1191, will be enforced for the location in Table 1 to § 165.1191, Item number 22, from 8 p.m. to 8:20 p.m. on October 9, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email MST1 Shannon Curtaz-Milian, Waterways Management, U.S. Coast Guard Sector San Francisco; telephone (415) 399–7440, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 22, for the Monte Foundation Fireworks Display from 8 p.m. to 8:20 p.m. on October 9, 2022. The Captain of the Port has delegated the authority to issue the notification of enforcement for this regulation to the Prevention Department Head.

The safety zone will extend to all navigable waters around the land-based launch site at the Capitola Pier in Capitola, CA. During the 20-minute fireworks display, scheduled to begin at approximately 8 p.m. on October 9, 2022, the safety zone will encompass navigable waters around and under the fireworks launch site within a radius of 1,000 feet in approximate position 36°58′09.92″ N, 121°57′15.06″ W (NAD 83) for the Monte Foundation Fireworks Display.

This safety zone will be enforced from 8 p.m. until 8:20 p.m. on October 9, 2022, or as announced via Broadcast Notice to Mariners. In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM or other Official Patrol defined as a Federal, state, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. Additionally, each person who receives notice of a lawful order or direction issued by the PATCOM or Official Patrol shall obey the order or direction. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: September 23, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2022–21097 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0759]

Safety Zone; Rio Vista Bass Derby Fireworks, Sacramento River, Rio Vista, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Rio Vista Bass Derby Fireworks Display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM) or other Federal, State, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulations in 33 CFR 165.1191, will be enforced for the location in Table 1 to § 165.1191, Item number 23, from 10 a.m. through 9:30 p.m. on October 8, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email MST1 Shannon Curtaz-Milian, Waterways Management, U.S. Coast Guard Sector San Francisco; telephone (415) 399–7440, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191 Table 1, Item number 23, for the Rio Vista Bass Derby Fireworks Display from 10 a.m. through 9:30 p.m. on October 8, 2022.

The safety zone will extend to all navigable waters of the Sacramento River, from surface to bottom, within a circle formed by connecting all points 100 feet out from the fireworks barge during the loading, transit, and arrival of the fireworks barge from the loading location to the display location and until the start of the fireworks display. From 10 a.m. through 4 p.m. October 8, 2022, the fireworks barge will load pyrotechnics from the Dutra Group, Oly Yard 615 River Road, Rio Vista, CA. The fireworks barge will remain at the loading location until its transit to the

display location. From 7:45 p.m. to 7:55 p.m. on October 8, 2022 the loaded fireworks barge will transit from the Dutra Group, Oly Yard 615 River Road, Rio Vista, CA to the launch site off of Rio Vista, CA in approximate position 38°09′16.00″ N, 121°41′17.00″ W (NAD 83), where it will remain until the conclusion of the fireworks display. During the 15-minute fireworks display, scheduled to begin at approximately 8:45 p.m. on October 8, 2022, and 30 minutes after the conclusion of the fireworks display, the safety zone will increase in size and encompass all navigable waters of the Sacramento River, from surface to bottom, within a circle formed by connecting all points 1000 feet out from the fireworks barge near Rio Vista, CA in approximate position 38°09′16.00″ N, 121°41′17.00″ W (NAD 83). This safety zone will be enforced from 10 a.m. until 9:30 p.m. on October 8, 2022, or as announced via Broadcast Notice to Mariners.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM or other Official Patrol defined as a federal, state, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. Additionally, each person who receives notice of a lawful order or direction issued by the PATCOM or Official Patrol shall obey the order or direction. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: September 23, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2022–21098 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0483]

RIN 1625–AA87

Security Zone; San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a security zone in the navigable waters of the San Francisco Bay near Yerba Buena Island within the San Francisco Captain of the Port (COTP) zone. This security zone is necessary to provide for the security of military service members onboard vessels moored at the pier and the government property associated with these valuable national assets. This regulation will prohibit the entry of, transiting through, or anchoring within a portion of the San Francisco Bay extending from Yerba Buena Island unless specifically authorized by the Captain of the Port San Francisco.

DATES: This rule is effective October 31, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0483 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email LT William Harris, Sector San Francisco, U.S. Coast Guard; telephone 415–399–7443, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

In October 2021, the Captain of the Port (COTP) San Francisco identified a need for clearer Aids to Navigation to inform the boating public of restricted areas near Yerba Buena Island. Further discussion discovered that current regulations established a Restricted Area, but not a Security Zone. The COTP has determined that potential security concerns associated with the mooring of Coast Guard Cutters necessitate a Coast Guard Security Zone.

In response, on July 18, 2022 the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Security Zone; San Francisco Bay, San Francisco, CA'' (87 FR 42665). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended August 17, 2022, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The purpose of this rule is to ensure the security of Coast Guard facilities, personnel, and vessels, at all times within the navigable waters of the San Francisco Bay on the east side of Yerba Buena Island from a point along the southeastern shore of Yerba Buena Island at 37°48′27″ N, 122°21′44″ W; east to 37°48′27″ N, 122°21′35″ W; north to 37°48′49″ N, 122°21′35″ W, a point on the northeastern side of Yerba Buena Island.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published July 18, 2022. There are no changes in the regulatory text of this rule from the regulatory text in the NPRM.

This rule establishes a security zone within the navigable waters of the San Francisco Bay on the east side of Yerba Buena Island from a point along the southeastern shore of Yerba Buena Island at 37°48′27″ N, 122°21′44″ W; east to 37°48′27″ N, 122°21′35″ W; north to 37°48′49″ N, 122°21′35″ W, a point on the northeastern side of Yerba Buena Island. No vessel or person will be permitted to enter the security zone unless authorized by the COTP.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 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. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size and location of the security zone. The effect of this rule will not be significant because vessel traffic can pass safely around the area, and this rule will encompass only a small portion of the waterway.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the security zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a security zone that would prohibit entry within navigable waters of the San Francisco Bay on the east side of Yerba Buena Island from a point along the southeastern shore of Yerba Buena Island at 37°48′27″ N, 122°21′44″ W; east to 37°48′27″ N, 122°21′35″ W; north to 37°48′49″ N, 122°21′35″ W, a point on the northeastern side of Yerba Buena Island. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.1189 to read as follows:

§ 165.1189 Security Zone; San Francisco Bay, San Francisco, CA.

(a) *Location.* The following area is a security zone: all navigable waters of the San Francisco Bay on the east side of Yerba Buena Island from a point along the southeastern shore of Yerba Buena Island at 37°48′27″ N, 122°21′44″ W; east to 37°48′27″ N, 122°21′35″ W; north to 37°48′49″ N, 122°21′35″ W, a point on the northeastern side of Yerba Buena Island. These coordinates are based on North American Datum (NAD) 83.

(b) *Regulations.* (1) In accordance with the general security zone regulations in subpart D of this part, entry into the area of the security zone described in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port (COTP) San Francisco.

(2) The security zone is closed to all vessel traffic, except as may be permitted by the COTP.

(3) To seek permission to enter, contact the COTP by VHF Marine Radio channel 16 or through the 24-hour Command Center at telephone (415) 399–3547. Those in the security zone must comply with all lawful orders or directions given to them by the COTP.

(c) *Enforcement.* The Captain of the Port will enforce the security zone described in paragraph (a) of this section and may be assisted in the patrol and enforcement of this security zone by any Federal, State, county, municipal, or private agency.

Dated: September 23, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2022–21093 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2019–0494; FRL–7584–03–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (19–4.F); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of Monday, June 27, 2022, concerning significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs). This document corrects a typographical error in an amendatory instruction.

DATES: This correction is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: *wysong.william@epa.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2022–13338 appearing on page 37999 in the **Federal Register** of Monday, June 27, 2022 (87 FR 37999 (FRL–7584–01–OCSPP)), the following correction is made to correct a typographical error in amendatory instruction 2:

■ 1. On page 38003, in the third column, in amendatory instruction 2 amending § 9.1, in the fourth and fifth lines, ''721.11404 through 721.11410, and 721.11411'' is corrected to read ''721.11404 through 721.11409, and 721.11411''.

Dated: September 23, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2022–20983 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2021–0030; FRL–8805–02–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (21–2.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs). The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

DATES: This rule is effective on November 28, 2022. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on October 13, 2022.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: *wysong.william@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:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. How can I access the dockets?

The dockets include information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0030, is available at *https://www.regulations.gov* and at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. Background

A. What action is the Agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for certain chemical substances which were the subject of PMNs. Previously, EPA proposed SNURs for these chemical substances and established the record for these SNURs in the following **Federal Register** and docket ID number:

- November 24, 2021 (86 FR 66993) (FRL–8805–01–OCSPP); Docket ID No. EPA–HQ–OPPT–2021–0030.

The docket includes information considered by the Agency in developing the proposed and final rules, including public comments and EPA's responses to the public comments received.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register** a statement of EPA's findings.

III. Significant New Use Determination

A. Considerations for Significant New Use Determinations

When the Agency issues an order under TSCA section 5(e), section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the TSCA Order or publish a statement describing the reasons for not initiating the rulemaking. TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

B. Procedures for Significant New Uses Claimed as CBI

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential.

Under the procedures in 40 CFR part 721.11 a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will identify any confidential significant new use designations under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step to identify if a chemical substance is subject to part 721 and if a specific use would be a significant new use under the rule.

IV. Public Comments on Proposed Rule and EPA Responses

EPA received public comments from two identifying entities on the proposed rule. The Agency's responses are presented in the Response to Public Comments document that is available in the public docket for this rulemaking. EPA made no changes to the proposed rule as described in the response to comments. EPA is not finalizing the rule for P–18–65 at this time as explained in the response to comments.

V. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E. In Unit IV. of the proposed SNURs, EPA provided the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as confidential business information (CBI)).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Effective date of and basis for the TSCA Order.
- Potentially Useful Information. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.
- CFR citation assigned in the regulatory text section of these rules.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume

limits and other uses designated in the rules, may be claimed as CBI.

These final rules include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The final SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs and as further discussed in Unit IV. of the proposed rule, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on such findings, TSCA Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors—not just the original submitter—are held to the same standard.

B. Objectives

EPA is issuing these SNURs because the Agency wants to

- Receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- Have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use; and
- Be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *https://www.epa.gov/tsca-inventory.*

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA Orders have been issued for all the chemical substances that are the subject of this rule, and the PMN submitters are prohibited by the TSCA Orders from undertaking activities which will be designated as significant new uses. The identities of many of the chemical substances subject to this rule have been claimed as confidential (per 40 CFR 720.85). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Furthermore, EPA designated the publication dates of the proposed rule (see Unit II.) as the cutoff dates for determining whether the new uses are ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of the above-mentioned dates, that person will have to cease any such activity upon the effective date of the final rule. To resume their activities, that person would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, TSCA Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to them or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs listed in this document. Descriptions are provided for informational purposes. The information identified in Unit IV. of the proposed rule will be potentially useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/*

alternative-test-methods-and-strategies-reduce.

In some of the TSCA Orders for the chemical substances identified in this rule, EPA has established production volume and time limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. The SNURs contain the same limits as the TSCA Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the TSCA Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information identified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance associated with the designated significant new uses. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analyses are available in the docket listed in Unit II.

XI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action establishes SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not subject to Executive Order 13771 (82 FR 9339, February 3, 2017), because this action is not a significant regulatory action under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The information collection requirements associated with SNURs have already been approved by OMB pursuant to the PRA under OMB control number 2070–0012 (EPA ICR No. 574). This rule does not impose any burden requiring additional OMB approval.

The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**,are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. The Information Collection Request (ICR) covering the SNUR activities was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

D. Regulatory Flexibility Act (RFA)

Pursuant to the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such

activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 10 in Federal fiscal year (FY) FY2016, 14 in FY2017, 16 in FY2018, five in FY2019, seven in FY2020, and 13 in FY2021, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $19,020 to $3,330. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about $11,164 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

E. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

F. Executive Order 13132: Federalism

This action will not have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

G. Executive Order 13175: Consultation and Coordination With Indian Tribe Governments

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

L. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information 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

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 23, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, amend the table by adding entries for §§ 721.11635 through 721.11658 in numerical order under the undesignated center heading ''Significant New Uses of Chemical Substances'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Significant New Uses of Chemical Substances	
* * * * *	
721.11635	2070–0012
721.11636	2070–0012
721.11637	2070–0012
721.11638	2070–0012
721.11639	2070–0012
721.11640	2070–0012
721.11641	2070–0012

40 CFR citation	OMB control No.
721.11642	2070–0012
721.11643	2070–0012
721.11644	2070–0012
721.11645	2070–0012
721.11646	2070–0012
721.11647	2070–0012
721.11648	2070–0012
721.11649	2070–0012
721.11650	2070–0012
721.11651	2070–0012
721.11652	2070–0012
721.11653	2070–0012
721.11654	2070–0012
721.11655	2070–0012
721.11656	2070–0012
721.11657	2070–0012
721.11658	2070–0012

* * * * *

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PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

Subpart E—Significant New Uses for Specific Chemical Substances

■ 4. Add §§ 721.11635 through 721.11658 to subpart E to read as follows:

Sec.

* * * * *

721.11635 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-.

721.11636 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(2-hydroxyethyl)-.

721.11637 1,3-Propanediamine, N1,N1-dimethyl-N3-(2,2,6,6-tetramethyl-4-piperidinyl)-.

721.11638 2-Propenoic acid, polymer with aliphatic cyclic epoxide (generic).

721.11639 1-Butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-oxazolidinyl)phenyl]-2-(phenylmethyl)-.

721.11640 Acrylic acid, tricyclo alkyl ester (generic).

721.11641 Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C12–14-alkyl ethers, phosphates, sodium salts.

721.11642 N-alkyl heteromonocyclic diphenolamide (generic).

721.11643 Reaction products of alkyl-terminated alkylalumuminoxanes and [[(pentaalkylphenyl-(pentaalkylphenyl)amino)alkyl] alkanediaminato]bis(aralkyl) transition metal coordination compound (generic).

721.11644 Multi-walled carbon nanotubes (generic).

721.11645 Carbomonocyclic sulfonium, salt with trihalo-sulfoalkyl hydroxycarbopolycyclic carboxylate (generic).

721.11646 Heterocyclic onium compound with 1-substituted-alkyl 2,2,2-trisubstitutedalkyl 2-methyl-2-propenoate (1:1) polymer with acenaphthylene, 4-ethenyl-a,a-dimethylbenzenemethanol and 4-ethenylphenyl acetate, hydrolyzed (generic).

721.11647 Sulfonium, triphenyl-, 1,2-substituted-alkyltricycloalkyl-1-carboxylate (1:1) (generic).

721.11648 N-substituted-beta-alanine, heterosubstituted-alkyl ester, ion(1-), triphenyl sulfonium (1:1) (generic).

721.11649 Sulfonium, [4-(1,1-dimethylethyl)phenyl]diphenyl-, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (generic).

721.11650 Dibenzothiophenium, 5-phenyl-, salt with 2,2-diheterosubstituted-2-sulfoethyl substituted-heterotricycloalkane-carboxylate (1:1) (generic).

721.11651 Substituted heterocyclic onium compound, salt with heteropolysubstitutedalkyl substitutedtricycloalkanecarboxylate (1:1), polymer with disubstituted aromatic compound and 1-methylcyclopentyl 2-methyl-2-propenoate, di-Me 2,2'-(1,2-diazenediyl)bis[2-methylpropenoate]-initiated (generic).

721.11652 Substituted-2H-thiopyrylium, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (generic).

721.11653 Sulfonium, triphenyl-, salt with 2,2-dihalo-2-sulfoethyl-2-oxo substituted-heterotricycloalkane-heteropolycyclo-carboxylate (1:1) (generic).

721.11654 Sulfonium, triphenyl-, salt with 5-alkyl-2-alkyl-4-(2,4,6-substituted tricarbomonocycle, hetero-acid) benzenesulfonate (1:1) (generic).

721.11655 Phenoxanthiinium, 10-phenyl, 5-alkyl-2-alkyl-4-(2,4,6-substituted tricarbomonocycle, hetero-acid) benzenesulfonate (1:1) (generic).

721.11656 Substituted, triaryl-, tricycloalkane alkyl disubstituted (generic) (P–20–156).

721.11657 Substituted, triaryl-, tricycloalkane alkyl disubstituted (generic) (P–20–162).

721.11658 Naphthalene derivative (generic).

§ 721.11635 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro- (PMN P–09–477; CAS No. 30334–69–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11636 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(2-hydroxyethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(2-hydroxyethyl)- (PMN P–09–485; CAS No. 34455–00–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11637 1,3-Propanediamine, N1,N1-dimethyl-N3-(2,2,6,6-tetramethyl-4-piperidinyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,3-propanediamine, N1,N1-dimethyl-N3-(2,2,6,6-tetramethyl-4-piperidinyl)- (PMN P–18–65; CAS No. 78014–16–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as an absorption agent or as a laboratory reagent. It is a significant new use to unload the substance other than under a gas (*e.g.* nitrogen) blanket. It is a significant new use to process the substance other than as described in the PMN or without additional steps that would reduce air emissions.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11638 2-Propenoic acid, polymer with aliphatic cyclic epoxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2-propenoic acid, polymer with aliphatic cyclic epoxide (PMN P–18–303) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11639 1-Butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-oxazolidinyl)phenyl]-2-(phenylmethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-

oxazolidinyl)phenyl]-2-(phenylmethyl)- (PMN P–18–345; CAS No. 2230995–63–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11640 Acrylic acid, tricyclo alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as acrylic acid, tricyclo alkyl ester (PMN P–18–351) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin sensitization; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=13.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11641 Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C12–14-alkyl ethers, phosphates, sodium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C12–14-alkyl ethers, phosphates, sodium salts (PMN P–19–48; CAS No. 1548592–90–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11642 N-alkyl heteromonocyclic diphenolamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as N-alkyl heteromonocyclic diphenolamide (PMN P–20–26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10,000. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin corrosion; eye irritation; serious eye damage; reproductive toxicity; specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may cause: aquatic toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g) and (t).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=41.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11643 Reaction products of alkyl-terminated alkylalumuminoxanes and [[(pentaalkylphenyl-(pentaalkylphenyl)amino)alkyl]alkanediaminato]bis(aralkyl) transition metal coordination compound (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as reaction products of alkyl-terminated alkylalumuminoxanes and [[(pentaalkylphenyl-(pentaalkylphenyl)amino)alkyl]alkanediaminato]bis(aralkyl) transition metal coordination compound (PMN P–20–46) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 0.1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3), and (g)(5). For purposes of § 721.72(e), the concentration is set at 0.1%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; skin irritation; serious eye damage; carcinogenicity; reproductive toxicity; specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may cause: aquatic toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(a) through (c).

(iv) *Disposal.* Requirements as specified in § 721.85(b)(1) and (c)(1). It is a significant new use to release the PMN substance directly to air.

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11644 Multi-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–20–72) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (5), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must include a N–100, P–100, or R–100 cartridge and provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: eye irritation; respiratory sensitization; skin sensitization; carcinogenicity; specific

target organ toxicity. For purposes of § 721.72(g)(3), this substance may cause: unknown aquatic toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k) and (t). It is a significant new use to import the substance such that the maximum weight percentage of the confidential impurity exceeds the confidential percentage specified in the Order. It is a significant new use to import the substance other than as confidentially described in the PMN and allowed by the Order. It is a significant new use to process or use the substance in application methods that generate a dust, mist, spray, vapor, or aerosol unless such application method occurs in an enclosed process.

(iv) *Disposal.* Requirements as specified in § 721.85(b)(1), (b)(2), (c)(1), and (c)(2). It is a significant new use to release the PMN substance directly to air.

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11645 Carbomonocyclic sulfonium, salt with trihalo-sulfoalkyl hydroxycarbopolycyclic carboxylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbomonocyclic sulfonium, salt with trihalo-sulfoalkyl hydroxycarbopolycyclic carboxylate (PMN P–20–120) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11646 Heterocyclic onium compound with 1-substituted-alkyl 2,2,2-trisubstitutedalkyl 2-methyl-2-propenoate (1:1) polymer with acenaphthylene, 4-ethenyl-a,a-dimethylbenzenemethanol and 4-ethenylphenyl acetate, hydrolyzed (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heterocyclic onium compound with 1-substituted-alkyl 2,2,2-trisubstitutedalkyl 2-methyl-2-propenoate (1:1) polymer with acenaphthylene, 4-ethenyl-a,a-dimethylbenzenemethanol and 4-ethenylphenyl acetate, hydrolyzed (PMN P–20–122) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a

significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11647 Sulfonium, triphenyl-, 1,2-substituted-alkyltricycloalkyl-1-carboxylate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, triphenyl-, 1,2-substituted-alkyltricycloalkyl-1-carboxylate (1:1) (PMN P–20–139) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11648 N-substituted-beta-alanine, heterosubstituted-alkyl ester, ion(1-), triphenyl sulfonium (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as n-substituted-beta-alanine, heterosubstituted-alkyl ester, ion(1-), triphenyl sulfonium (1:1) (PMN P–20–140) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11649 Sulfonium, [4-(1,1-dimethylethyl)phenyl]diphenyl-, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, [4-(1,1-dimethylethyl)phenyl]diphenyl-, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (PMN P–20–141) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11650 Dibenzothiophenium, 5-phenyl-, salt with 2,2-diheterosubstituted-2-sulfoethyl substituted-heterotricycloalkane-carboxylate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dibenzothiophenium, 5-phenyl-, salt with 2,2-diheterosubstituted-2-sulfoethyl substituted-heterotricycloalkane-carboxylate (1:1) (PMN P–20–142) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11651 Substituted heterocyclic onium compound, salt with heteropolysubstitutedalkyl substitutedtricycloalkanecarboxylate (1:1), polymer with disubstituted aromatic compound and 1-methylcyclopentyl 2-methyl-2-propenoate, di-Me 2,2′-(1,2-diazenediyl)bis[2-methylpropenoate]-initiated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted heterocyclic onium compound, salt with heteropolysubstitutedalkyl substitutedtricycloalkanecarboxylate (1:1), polymer with disubstituted aromatic compound and 1-methylcyclopentyl 2-methyl-2-propenoate, di-Me 2,2′-(1,2-diazenediyl)bis[2-methylpropenoate]-initiated (PMN P–20–145) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as

specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11652 Substituted-2H-thiopyrylium, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted-2H-thiopyrylium, salt with heterosubstituted-alkyl tricycloalkane-carboxylate (1:1) (PMN P–20–147) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11653 Sulfonium, triphenyl-, salt with 2,2-dihalo-2-sulfoethyl-2-oxo substituted-heterotricycloalkane-heteropolycyclo-carboxylate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, triphenyl-, salt with 2,2-dihalo-2-sulfoethyl-2-oxo substituted-heterotricycloalkane-heteropolycyclo-carboxylate (1:1) (PMN P–20–152) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11654 Sulfonium, triphenyl-, salt with 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbomonocycle, hetero-acid) benzenesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, triphenyl-, salt with 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbomonocycle, hetero-acid) benzenesulfonate (1:1) (PMN P–20–155) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not

apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11655 Phenoxanthiinium, 10-phenyl, 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbomonocycle, hetero-acid) benzenesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenoxanthiinium, 10-phenyl, 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbomonocycle, hetero-acid) benzenesulfonate (1:1) (PMN P–20–159) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11656 Substituted, triaryl-, tricycloalkane alkyl disubstituted (generic) (P–20–156).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted, triaryl-, tricycloalkane alkyl disubstituted (PMN P–20–156) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless

in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11657 Substituted, triaryl-, tricycloalkane alkyl disubstituted (generic) (P–20–162).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted, triaryl-, tricycloalkane alkyl disubstituted (PMN P–20–162) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

§ 721.11658 Naphthalene derivative (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as naphthalene derivative (PMN P–21–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; skin sensitization; germ cell mutagenicity; reproductive toxicity; specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may cause: aquatic toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (k).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.11 apply to paragraph (a)(2)(iii) of this section.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0798; FRL–10218–01–R9]

Finding of Failure To Submit Contingency Measures for the 2008 8-Hour Ozone NAAQS; Coachella Valley, California, and West Mojave Desert, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to find that the State of California has failed to submit State Implementation Plan (SIP) revisions to satisfy the contingency measures requirements of the Clean Air Act (CAA) for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or ''standards'') for both the Riverside County (Coachella Valley), California (''Coachella Valley'') and Los Angeles-San Bernardino Counties (West Mojave Desert), California (''West Mojave

Desert'') nonattainment areas. Under the CAA and the EPA's implementing regulations, by July 20, 2016, California was required to submit, among other SIP revisions, contingency measures for the Coachella Valley and West Mojave Desert nonattainment areas to be triggered if the areas fail to attain or fail to meet reasonable further progress (RFP). The State submitted the required SIP revisions, but subsequently withdrew the contingency measures portion. This finding establishes a 2-year deadline for the EPA to promulgate Federal Implementation Plans (FIPs) to address the contingency measure requirements for these areas, unless, prior to the EPA promulgating FIPs, California submits, and the EPA approves, SIP revisions that meet these requirements. The CAA also provides for the imposition of sanctions if California does not submit the required SIP revisions within timeframes specified by the CAA.

DATES: This final action is effective on October 31, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Dorantes, Air Planning Office (AIR–2), EPA Region IX, (415) 972–3934, *dorantes.michael@epa.gov.*

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

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I. Notice and Comment Under the Administrative Procedure Act (APA)

Section 553 of the APA, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this final agency action without prior proposal and opportunity for comment because no significant EPA judgment is involved in making findings of failure to submit SIPs, or elements of SIPs, required by the CAA, where states and territories have made no submissions, or incomplete submissions, to meet the requirement. Thus, notice and public procedures are unnecessary. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

II. Background and Overview

A. Ozone Standards, Area Designations, and SIP Development

Under section 109 of the CAA, the EPA promulgates NAAQS for pervasive air pollutants, such as ozone. In 2008, the EPA promulgated new 8-hour primary and secondary ozone NAAQS of 0.075 ppm (''2008 ozone NAAQS'') to replace the 1997 ozone NAAQS of 0.08 ppm.[1] Although the EPA further strengthened the 8-hour ozone NAAQS to 0.070 ppm in 2015, this action relates to the requirements for the 2008 ozone NAAQS.[2] Following promulgation of new or revised NAAQS, the EPA is required by the CAA to designate areas throughout the nation as either attaining or not attaining the standards. Effective July 20, 2012, the EPA designated both Coachella Valley and West Mojave Desert as nonattainment for the 2008 ozone NAAQS and classified the areas as ''Severe-15.'' [3] Areas designated nonattainment for ozone NAAQS are subject to the general nonattainment area planning requirements of CAA section 172 and to the ozone-specific planning requirements of CAA section 182.

On March 6, 2015, the EPA published a final implementation rule for the 2008 ozone NAAQS, detailing the requirements applicable to ozone nonattainment areas and providing specific deadlines for SIP submittals.[4] For areas classified Serious and above, the SIP revisions providing for an attainment demonstration, RFP demonstration, and attainment and RFP contingency measures were due 4 years after the effective date of area designations (*i.e.,* by July 20, 2016).[5] Contingency measures are additional controls or measures to be implemented in the event an area fails to make RFP or to attain the NAAQS by the attainment date.

In California, the California Air Resources Board (CARB) is the agency responsible for the adoption and submission to the EPA of SIPs and SIP revisions. Working jointly with CARB, local and regional air pollution control districts in California are responsible for the development of regional air quality plans. The South Coast Air Quality Management District (SCAQMD) develops and adopts plans to address CAA planning requirements applicable to the Coachella Valley. The Antelope Valley Air Quality Management District (AVAQMD) and Mojave Desert Air Quality Management District (MDAQMD) share responsibility for air quality planning in the West Mojave Desert. These agencies adopt and submit their plans to CARB for state adoption and submission to the EPA as revisions to the California SIP.

B. State Submissions and Withdrawals

CARB submitted contingency measures for the 2008 ozone NAAQS for the Coachella Valley in the *Final 2016 Air Quality Management Plan (March 2017)* (''2016 AQMP''), submitted on April 27, 2017,[6] the *Coachella Valley 8-Hour Ozone Attainment Contingency* (''Coachella Attainment Contingency'') submitted on May 5, 2017,[7] and the *2018 Updates to the California State Implementation Plan* (''2018 SIP Update'') submitted on December 5, 2018. On September 16, 2020, the EPA approved the relevant portions of these SIP revisions as meeting all applicable ozone nonattainment area requirements for the 2008 ozone NAAQS in the Coachella Valley, except for the contingency measure requirements, for which the EPA deferred action.[8]

CARB submitted contingency measures for the 2008 ozone NAAQS for the West Mojave Desert in a SIP revision submitted on June 2, 2017.[9] This submittal includes attainment plans prepared by the AVAQMD (''AVAQMD Attainment Plan'') [10] and the MDAQMD (''MDAQMD Attainment Plan''),[11] an accompanying staff report prepared by CARB (''CARB Staff Report''),[12] and other supporting documents. We refer to all the documents collectively submitted to the EPA on June 2, 2017 as the ''2016 WMD Attainment Plan.'' Some elements of the 2016 WMD Attainment Plan were updated for the

[1] 73 FR 16436 (March 27, 2008).

[2] Information on the 2015 ozone NAAQS is available at 80 FR 65292 (October 26, 2015).

[3] 77 FR 30088 (May 21, 2012).

[4] 80 FR 12264 (March 6, 2015).

[5] 40 CFR 51.1108(b) and 40 CFR 51.1110.

[6] Letter dated April 27, 2017, from Richard Corey, Executive Officer, CARB, to Alexis Strauss, Acting Regional Administrator, EPA Region IX.

[7] Letter dated May 5, 2017, from Richard Corey, Executive Officer, CARB, to Alexis Strauss, Acting Regional Administrator, EPA Region IX.

[8] 85 FR 57714 (September 16, 2020).

[9] Letter dated June 2, 2017, from Richard Corey, Executive Officer, CARB, to Alexis Strauss, Acting Regional Administrator, EPA Region IX.

[10] AVAQMD, ''AVAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area),'' adopted on March 21, 2017.

[11] MDAQMD, ''MDAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area),'' adopted on February 27, 2017.

[12] CARB, Staff Report, ''CARB Review of the Mojave Desert AQMD and Antelope Valley AQMD Federal 75 ppb Ozone Attainment Plans for the Western Mojave Desert Nonattainment Area,'' released April 21, 2017.

West Mojave Desert nonattainment area in the 2018 SIP Update. On September 27, 2021, the EPA took final action to approve the relevant portions of the 2016 WMD Attainment Plan and 2018 SIP Update as meeting all the applicable ozone nonattainment area requirements, except for the contingency measure requirements, for which the EPA deferred action.[13] CARB subsequently submitted additional contingency measures provisions in the *Amendment to the 75 ppb 2008 8hr O3 Contingency Measure for MDAQMD portion of the Western Mojave Desert Nonattainment Area* (''MDAQMD Contingency Amendment'') on February 1, 2022.[14]

On August 26, 2021, following CARB's submittals for the Coachella Valley and West Mojave Desert, the U.S. Court of Appeals for the Ninth Circuit remanded the EPA's conditional approval of contingency measures for the 2008 ozone NAAQS for the San Joaquin Valley nonattainment area, finding that the EPA had not provided a reasoned explanation for considering emission reductions from already-implemented measures.[15] CARB subsequently withdrew the contingency measures elements of the 2016 AQMP, the Coachella Attainment Contingency, and the relevant portions of the 2018 SIP Update (for the Coachella Valley), and the contingency measures elements of the 2016 WMD Attainment Plan, the relevant portions of the 2018 SIP Update, and the MDAQMD Contingency Amendment (for the West Mojave Desert),[16] following requests from the local air districts.[17]

III. Final Action and Consequences of a Finding of Failure To Submit

Based upon the withdrawal of the contingency measures described in Section II of this rulemaking, the EPA is finding that California has failed to make required submittals for the 2008 ozone NAAQS for the Coachella Valley and West Mojave Desert nonattainment areas. With this finding, section 179 of the CAA starts sanctions clocks and a FIP clock. Section 179(a) of the CAA specifies the consequences if the EPA finds that a state has failed to make a required SIP submission, if the EPA has determined that a submitted SIP is incomplete, or if the EPA has disapproved a SIP submission. If the EPA has not affirmatively determined that California has made complete submissions to address the contingency measures requirements for the Coachella Valley or West Mojave Desert nonattainment areas within 18 months of the effective date of this action, the offset sanction identified in section 179(b)(2) will apply within that area, pursuant to section 179(a) and (b) and 40 CFR 52.31. If the EPA has not affirmatively determined that California has made a complete SIP submission for either area within six months after imposition of the offset sanction, the highway funding sanction will be imposed, as required under section 179(b)(1) of the CAA and 40 CFR 52.31.

California may avoid these sanctions by taking timely action to remedy this finding. The 18-month clock governing the CAA's imposition of sanctions for these areas will stop and sanctions will not take effect if the EPA finds that the State has made a complete SIP submission addressing the contingency measures requirements for these areas area within 18 months of the date of this finding. Similarly, the EPA is not required to promulgate a FIP if California makes the required SIP submissions, and the EPA takes final action to approve the submissions within two years of this finding of failure to submit a required SIP. In sum, the CAA does not require sanctions or a FIP if the State and the EPA take timely action to remedy this finding.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *http://www2.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 not a significant regulatory action and therefore was not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA because it does not impose additional requirements beyond those imposed by state law.

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 beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA (2 U.S.C. 1531–1538) and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

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, because this action does not 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, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

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[13] 86 FR 53223 (September 27, 2021).

[14] Letter dated January 31, 2022, from Richard W. Corey, CARB, to Martha Guzman, Regional Administrator, EPA Region IX.

[15] *Association of Irritated Residents* v. *EPA,* 10 F.4th 937 (9th Cir. 2021).

[16] See two letters dated August 8, 2022, from Edie Chang, Deputy Executive Officer to Martha Guzman, Regional Administrator, USEPA Region IX, addressing Coachella Valley and West Mojave Desert.

[17] See letter dated June 24, 2022, from Wayne Nastri, Executive Officer, SCAQMD, to Richard Corey, Executive Officer, CARB and letters dated June 30, 2022, from Bret Banks, Executive Director/APCO, AVAQMD, and Brad Poiriez, Executive Director/APCO, MDAQMD, to Sylvia Vanderspek, Air Quality Planning Branch Chief, CARB.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (February 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health effects of their programs, policies, and activities on minority populations and low-income populations in the United States. There is no information in the record inconsistent with the stated goals of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

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).

L. Petitions for Judicial Review

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 November 28, 2022. Filing a petition for reconsideration by the Administrator of this final action 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, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

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

Dated: September 21, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2022–20874 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0408; FRL–8902–02–R9]

Clean Air Plans; Base Year Emissions Inventories for the 2015 Ozone Standards; California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the California State Implementation Plan (SIP) concerning the base year emissions inventories for 18 areas designated as nonattainment areas (NAAs) for the 2015 ozone national ambient air quality standards (''2015 ozone NAAQS'') submitted on July 24, 2020. The areas include Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County. We are approving these revisions under the Clean Air Act (CAA), which establishes emissions inventory requirements for all ozone nonattainment areas.

DATES: This rule is effective on October 31, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0408. 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 disabilities 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: Ben Leers, Air Planning Office (AIR–2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4279, or by email at *leers.ben@epa.gov.*

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

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I. Summary of Proposed Action

On October 5, 2021, in accordance with CAA sections 172(c)(3) and 182(a)(1), the EPA proposed to approve a July 27, 2020 SIP submittal from the California Air Resources Board (CARB) to address the ozone-related emissions inventory requirements for the following 18 ozone nonattainment areas for the 2015 ozone NAAQS: Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County.[1] We refer to our October 5, 2021 proposed rulemaking as the ''proposed rule.''

On October 28, 2021, the EPA extended the comment period for the proposed rule by 30 days in response to a stakeholder request for an extension.[2] The original deadline to submit comments was November 4, 2021. This action extended the comment period to December 6, 2021.

In our proposed rule, we provided background information on the 2015 ozone standards, area designations in

[1] 86 FR 54887 (October 5, 2021).

[2] 86 FR 59678 (October 28, 2021).

California, and related base year emissions inventory SIP revision requirements under the CAA and the EPA's implementing regulations for the 2015 ozone standards, referred to as the 2015 ozone SIP Requirements Rule (''2015 Ozone SRR'').[3]

On July 27, 2020, the California Air Resources Board (CARB) submitted the ''70 ppb Ozone SIP Submittal'' (''2020 CARB SIP Submittal'') to the EPA.[4] As explained in our proposed rule, the 2020 CARB SIP Submittal contains a staff report with a release date of May 22, 2020, and attachments of emissions inventories that address base year inventory requirements for 18 of the 21 NAAs in California.[5] In our proposed rule, we provided a summary of the 2020 CARB SIP Submittal, evaluated the submittal for compliance with statutory and regulatory requirements, and proposed to find that the submittal meets all applicable requirements.

The emissions inventories we are approving into the SIP in this final action are detailed in Table 1 of the proposed rule. The EPA finds that CARB developed approvable inventories of oxides of nitrogen (NO_X) and volatile organic compounds (VOC) emissions for the 18 ozone nonattainment areas as required under the CAA and 2015 Ozone SRR (40 CFR 51.1315; see also CAA section 172(c)(3)).

Refer to our proposed rule for more information concerning the background for this action and for a more detailed discussion of the rationale for approval.

II. Public Comments and EPA Responses

The EPA's proposed rule provided a 30-day public comment period that ended on November 4, 2021. As explained in section I of this preamble, on October 28, 2021, we extended the comment period by 30 days to December 6, 2021, in response to a stakeholder request for an extension.[6] We received eight sets of comments, including seven comment submissions from private individuals[7] and one comment letter from the Center for Biological Diversity (CBD).[8] All comments received in response to our proposed rulemaking are available in the docket for this rulemaking.[9] Four of the comment submissions from private individuals generally support our proposal to approve the 2020 CARB SIP Submittal as meeting the base year emissions inventory requirements.[10] These four supportive comments do not require a response. We respond to the remainder of the comments received on our proposed rulemaking in this action.

A. Comments From Private Individuals

Comment A.1: Two private individual commenters[11] question how the proposed rulemaking will improve air pollution in the nonattainment areas. Additionally, one of the commenters[12] suggests that there should be a call to action for these nonattainment areas to implement some forms of regulation or change in activities to actively pursue attainment of environmental goals.

Response A.1: The EPA appreciates the commenters' questions regarding how air pollution will be improved. As explained in our proposed rule, CAA section 182(a)(1) and 40 CFR 51.1315 require states to develop and submit, as SIP revisions, emissions inventories for all areas designated as nonattainment for the 2015 ozone NAAQS. An emissions inventory for an ozone nonattainment area is comprised of typical weekday actual emissions of ozone precursors in the area's ozone season. Emissions inventories provide emissions data for a variety of air quality planning tasks, including establishing baseline emissions levels (*i.e.,* the level of emissions associated with violations of the ozone standards), calculating emissions reduction targets needed to attain the NAAQS and to achieve reasonable further progress (RFP) toward attainment of the ozone standards, determining emissions inputs for ozone air quality modeling analyses, and tracking emissions over time to determine progress toward achieving air quality and emissions reduction goals.

The EPA also appreciates the commenters' concerns about nonattainment areas needing to actively pursue attainment via implementation of regulations or change in activities. The EPA promulgates NAAQS for certain air pollutants, such as ozone, under section 109 of the CAA. The NAAQS are concentration levels that the EPA has determined to be requisite to protect public health and welfare. Under CAA section 107(d), the EPA designates areas as nonattainment if they are violating the NAAQS or contributing to a violation of the NAAQS in nearby areas. State and local governments with nonattainment areas must develop implementation plans outlining how these areas will attain and maintain the NAAQS by reducing air pollutant emissions. Sections 110, 172, and 182 of the CAA require states to develop and submit SIPs to implement, maintain, and enforce the NAAQS.[13] These SIPs address requirements for emissions inventories, attainment demonstrations, reasonable further progress, reasonably available control measures, contingency measures, and motor vehicle emissions budgets to improve air quality. Although the base year emissions inventories submitted pursuant to CAA sections 172(c)(3) and 182(a)(1) are not intended to result directly in reductions of emissions or ozone concentration levels, they inform the development and implementation of the SIP submittals that are required under the CAA to actively pursue attainment of environmental goals, as suggested by the commenter.

Comment A.2: One private individual commenter[14] suggests that, within the requirements for base year inventories, a fifth class of anthropogenic sources should be added. The commenter explains that this fifth class will cover emissions contributions from agriculture livestock, agricultural soils, and rice production. The commenter indicates that by adding this fifth class,

[3] ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' Final Rule, 83 FR 62998 (December 6, 2018).

[4] Letter dated July 24, 2020, from Richard W. Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX (submitted electronically July 27, 2020).

[5] CARB's submittal does not include the San Diego NAA, which was submitted separately via the State Planning Electronic Collaboration System (SPeCS) for SIPs on January 12, 2021. The EPA will take action on the emissions inventory for the San Diego NAA in a separate rulemaking. Because the State of California does not have regulatory authority over the Pechanga and Morongo NAAs, CARB's submittal does not include emissions inventories for these areas.

[6] Email dated October 7, 2021, from Robert Ukeiley, Center for Biological Diversity, to Khoi Nguyen, EPA Region IX.

[7] Comments from private individuals were made to Docket ID No. EPA–R09–OAR–2021–0408 as follows: (1) comment dated October 6, 2021, from Saida Lopez Williams; (2) comment dated October 8, 2021, from Annie Miller; (3) comment dated October 11, 2021, from Tristan Sommers; (4) comment dated October 16, 2021, from Taylor W.; (5) comment dated November 3, 2021, from Lindsey H.; (6) comment dated November 3, 2021, from Alexander Mata; (7) comment dated November 3, 2021, from Tom Loch.

[8] Letter dated December 1, 2021, from Nathan Donley, Center for Biological Diversity, to Docket ID No. EPA–R09–OAR–2021–0408, Subject: ''Re: Comments on Clean Air Plans; Base Year Emission Inventories for the 2015 Ozone Standards; California (Docket #: EPA–R09–OAR–2021–0408).''

[9] Comments are publicly available at *https://www.regulations.gov/docket/EPA-R09-OAR-2021-0408/comments.*

[10] Docket ID No. EPA–R09–OAR–2021–0408–0011, EPA–R09–OAR–2021–0408–0014, EPA–R09–OAR–2021–0408–0015, and EPA–R09–OAR–2021–0408–0016.

[11] Docket ID No. EPA–R09–OAR–2021–0408–0007 and EPA–R09–OAR–2021–0408–0008.

[12] Docket ID No. EPA–R09–OAR–2021–0408–0008.

[13] For more information on the NAAQS implementation process, please see *https://www.epa.gov/criteria-air-pollutants/naaqs-implementation-process.*

[14] Docket ID No. EPA–R09–OAR–2021–0408–0009.

the proposed rule will gain a more thorough overview of ozone creation within California, allowing the EPA to make better decisions based on nonattainment areas.

Response A.2: As explained in our proposed rule, CAA section 182(a)(1) and 40 CFR 51.1315 contain the requirements for ozone base year emissions inventories. The EPA's guidance for the preparation of ozone base year emissions inventories (''EI Guidance'') [15] also indicates that, traditionally, the term ''source category'' has been used to identify the major types of emissions inventory groupings: stationary point sources, stationary area (or nonpoint) sources, on-road mobile sources, and nonroad mobile sources.[16] Accordingly, our proposed rule identifies four general classes of anthropogenic sources: stationary point sources; area sources; on-road mobile sources; and off-road mobile sources.

Potentially referring to section A.2 of our proposed rulemaking titled ''Requirements for Base Year Inventories,'' the commenter proposes that the requirements for base year inventories should be amended to add a requirement for a separate category of anthropogenic sources encompassing emissions from agriculture livestock, agricultural soils, and rice production. The requirements for base year emissions inventories established at 40 CFR 51.1315 and at CAA sections 172(c)(3) and 182(a)(1) do not define specific ''classes'' of sources in which to sort reported emissions. However, we note that the source categories cited by the commenter for inclusion in a ''fifth class,'' *i.e.,* agricultural livestock, agricultural soils, and rice production, are already included in California's base year emissions inventories for the 2015 ozone NAAQS. Emissions from these sources are accounted for in the 2020 CARB SIP Submittal under diesel agricultural equipment, agricultural diesel irrigation pumps, pesticides, farming operations (including livestock husbandry), and agricultural burning.[17]Additionally, we note that the EPA's EI Guidance addresses emissions from agricultural livestock [18] and from certain agricultural soil sources (*e.g.,* direct emissions of pesticides and fertilizers [19]) under the area source category. Emissions from rice production are addressed under various source categories, including the area source category for processes such as direct application of pesticides and fertilizers [20] and the non-road mobile source category for mobile agricultural equipment.[21]

Comment A.3: One private individual commenter [22] expresses concerns about the lack of base year emissions inventory updates for attainment areas and questions why emissions reductions or new emissions standards are not required for attainment areas.

Response A.3: While establishing requirements for nonattainment and attainment areas is outside the scope of this rulemaking action, the EPA agrees that protection of air quality in all areas is of vital importance. We note that the CAA imposes various requirements on nonattainment areas for ozone national ambient air quality standards. The requirements that apply to ozone nonattainment areas, including the requirement for states to submit base year emissions inventories for these areas, are established in CAA sections 172 and 182. These statutes apply specifically to areas that the EPA has determined to be in nonattainment with respect to a NAAQS and are intended to restore air quality in these areas to levels that the EPA has determined to be requisite to protect public health and welfare with an adequate margin for safety. Accordingly, the SIP submittal that the EPA is evaluating for this action was submitted to fulfill requirements specific to ozone nonattainment areas. The requirements in CAA sections 172 and 182 do not apply to areas designated as attainment, and there is no CAA requirement for states to submit base year emissions inventories for attainment areas.

We do note, however, that recent emissions information is available for all areas of the United States, including attainment areas, in the EPA's national emissions inventory (NEI). The NEI contains comprehensive and detailed information on air emissions of criteria pollutants, criteria pollutant precursors, and hazardous air pollutants from air emissions sources nationwide.[23] The NEI is released every three years and is based primarily upon data provided by state, local, and tribal air agencies for sources in their jurisdictions in accordance with the air emissions reporting requirements (AERR) at 40 CFR part 51, subpart A. At the state level, CARB also collects and provides statewide emissions via the California emissions inventory data analysis and reporting system (CEIDARS), which is a database management system developed to track statewide criteria pollutant and air toxics emissions.[24] Similarly to the NEI, CEIDARS includes emissions information for all areas in California and is not limited to nonattainment areas.

B. Comment From Center for Biological Diversity

Comment B.1: CBD asserts that CARB's base year emissions inventories must be corrected to account for anthropogenic sources of soil-based NO_X emissions related to fertilizer and pesticide use in California before the EPA may approve the inventories.[25] Throughout its comment letter, CBD refers to soil NO_X resulting from fertilizer and pesticide use as an anthropogenic emissions source. CBD implies that CARB assumes NO_X emissions from fertilizers and pesticides to be zero and argues that doing so is unacceptable and contrary to science. While the commenter acknowledges the challenges associated with quantifying NO_X emissions resulting from fertilizer and pesticide use, they consider the quantification of these emissions to be no more complex than CARB's quantification of VOC emissions from pesticides in its base year emissions inventories. CBD's comment letter discusses the impacts that both fertilizer and pesticide use have on NO_X emissions and cites 13 research manuscripts to support their comment, 11 of which are included as attachments to the comment letter.

[15] EPA, ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations'' (May 2017).

[16] EI Guidance, 19.

[17] 2020 CARB SIP Submittal, Staff Report, 13, 15, 20–22.

[18] EI Guidance, 87 and B–1.

[19] EI Guidance, 87–88.

[20] Id.

[21] EI Guidance, 27.

[22] Docket ID No. EPA–R09–OAR–2021–0408–0008.

[23] For more information on the NEI, please see *https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei.*

[24] See *https://ww2.arb.ca.gov/criteria-pollutant-emission-inventory-data.*

[25] CBD's comment letter and attachments (''CBD comment'') are available at *https://www.regulations.gov/* under Docket ID No. EPA–R09–OAR–2021–0408–0017.

With respect to fertilizer use, the commenter first references two studies: one concluding that non-fossil fuel NO_X emissions should be equally considered as fossil fuel NO_X emissions when designing NO_X pollution mitigation,[26] and another estimating that 600,000 to 800,000 tons of nitrogen from inorganic fertilizer were used in California each year between 2000 and 2008.[27] Additionally, the commenter cites a study finding that, while soils are always producing background NO_X in California, NO_X production rises considerably in croplands with high fertilizer use, and the NO_X emitted through soil could produce over 50 percent of the atmospheric NO_X present in rural California regions.[28] The commenter also references a review of studies conducted in California counties to suggest that between 0.2 and 10.4 percent of the nitrogen applied as fertilizer is emitted as NO_X, depending on the application method and region.[29] Further, the commenter cites a recent study finding that fertilized croplands account for 32 percent of NO_X emissions across California.[30] Lastly, the commenter references a study indicating that California has measured fluxes in NO_X in the San Joaquin Valley in the past and correlated these changes with fertilizer use.[31]

With respect to pesticide use, the commenter cites two recent studies to suggest that pesticides of all types can have negative impacts on soil invertebrates or microorganisms by killing or inducing sublethal effects on growth, behavior, or reproduction.[32] [33] Additionally, the commenter references research studies to suggest that the fumigant pesticide chloropicrin was found to increase soil NO_X emissions by 8-fold and 7-fold in laboratory and field conditions, respectively,[34] that multiple herbicides, one fungicide, and one adjuvant all increased NO_X emissions in agricultural soils two months after crop harvest,[35] that the herbicide butachlor increased NO_X emissions from citrus fields by 56–85 percent,[36] that application of the insecticide sulfoxaflor to greenhouse vegetables drives changes to soil microbial communities leading to increased NO_X emissions,[37] and that application of the fungicide chlorothalonil has similar impacts to soil microbial communities leading to increases of NO_X emissions in tea fields by 380–830 percent.[38]

Response B.1: We appreciate CBD's comment regarding the inclusion of soil NO_X emissions resulting from fertilizer and pesticide use in CARB's 2015 ozone base year emissions inventories. We acknowledge the studies cited by CBD in their comment letter finding that these types of soil NO_X emissions contribute to atmospheric NO_X levels in California. Particularly, the EPA acknowledges the growing body of research surrounding the identification and quantification of soil NO_X emissions induced by fertilizer application in agricultural soils. The EPA encourages CARB and the districts governing California's ozone nonattainment areas to perform and keep abreast of research on NO_X emissions from agriculture and their implications for air quality modeling and planning. However, as highlighted by our discussion in the following paragraphs, in light of EPA guidance and regulations related to the classification of emissions sources in base year emissions inventories and uncertainties and disagreements among studies regarding the contribution of fertilized cropland soils to NO_X emissions in California, the EPA disagrees with the commenter's assertion that the emissions inventories in the 2020 CARB SIP Submittal must be amended to account for soil NO_X emissions before the EPA may approve them as meeting the base year emissions inventory requirements for the 2015 ozone NAAQS.

The 2020 CARB SIP Submittal specifies that the emissions inventories in the submittal include only emissions from anthropogenic sources, *i.e.,* they do not include biogenic emissions.[39] CBD's comment letter frequently refers to soil NO_X from agricultural sources as an anthropogenic emissions source, suggesting that these soil NO_X emissions must be categorized as anthropogenic and thereby included in CARB's base year emissions inventories. However, the techniques currently available for the estimation of soil NO_X emissions induced by fertilizer application, including the techniques used in the studies cited by CBD in its comment letter, present substantial uncertainty and variability with respect to the magnitude and proportion of soil NO_X emissions that can be attributed to agricultural fertilizer application. Thus, at this time, we do not find CARB's base year emissions inventories to be deficient for not including soil NO_X as an anthropogenic emissions source.

In its comment letter, CBD acknowledges the ''highly variable'' nature of soil NO_X emissions and notes that estimating such emissions requires data on fertilizer or pesticide use in a particular region and is dependent on application method, amount of moisture in the soil and ''a whole host of other variables.'' [40] In a study cited by the commenter, Almaraz et al. highlight the uncertainty present in the soil NO_X estimation techniques relied upon in the

[26] Song et al. (2021). Important contributions of non-fossil fuel nitrogen oxides emissions, Nature Communications, 12(1), doi:10.1038/s41467–020–20356–0; available at *https://www.nature.com/articles/s41467-020-20356-0.*

[27] Rosenstock et al. (2013). Nitrogen fertilizer use in California: Assessing the data, trends and a way forward, California Agriculture, 67(1), 68–79, doi:10.3733/ca.e.v067n01p68; available at *https://escholarship.org/uc/item/5mk2q1sm.*

[28] Sha et al. (2021). Impacts of soil NO_X emission on O_3 air quality in rural California, Environmental Science & Technology, 55(10), 7113–7122, doi:10.1021/acs.est.0c06834; available at *https://pubs.acs.org/doi/10.1021/acs.est.0c06834.*

[29] Verhoeven et al. (2017). N_2O emissions from California farmlands: A review, California Agriculture, 71(3), 148–159, doi:10.3733/ca.2017a0026; *available at https://escholarship.org/uc/item/0kb4505k.*

[30] Almaraz et al. (2018). Agriculture is a major source of NO_X pollution in California, Science Advances, 4(1), doi:10.1126/sciadv.aao3477, 2018; available at *https://advances.sciencemag.org/content/4/1/eaao3477.*

[31] Matson et al. (1997). Agricultural Systems in the San Joaquin Valley: Development of Emissions Estimates for Nitrogen Oxides; available at *https://ww2.arb.ca.gov/sites/default/files/classic//research/apr/past/94-732.pdf.*

[32] Puglisi, E. (2012). Response of microbial organisms (aquatic and terrestrial) to pesticides, EFSA Supporting Publications, 9(11), doi:10.2903/sp.efsa.2012.en-359; available at *https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2012.EN-359.*

[33] Gunstone et al. (2021). Pesticides and soil invertebrates: A hazard assessment, Frontiers in Environmental Science, 9, doi:10.3389/fenvs.2021.643847; available at *https://www.frontiersin.org/articles/10.3389/fenvs.2021.643847/full.*

[34] Spokas and Wang. (2003). Stimulation of nitrous oxide production resulted from soil fumigation with chloropicrin, Atmospheric Environment, 37(25), 3501–3507, doi:10.1016/s1352–2310(03)00412–6; available at *https://www.sciencedirect.com/science/article/abs/pii/S1352231003004126.*

[35] Jezierska-Tys et al. (2021). Microbiological nitrogen transformations in soil treated with pesticides and their impact on soil greenhouse gas emissions, Agriculture, 11(8), 787, doi:10.3390/agriculture11080787; available at *https://www.mdpi.com/2077-0472/11/8/787.*

[36] XiangZhou et al. (2018). Effects of herbicides on urea nitrogen transformation and greenhouse gas emission of soil in citrus orchards with different planting years, Chinese Journal of Eco-Agriculture, 26(3), 338–346; available at *https://www.cabdirect.org/cabdirect/abstract/20183141714.*

[37] Fang et al. (2021). Effects of sulfoxaflor on greenhouse vegetable soil N_2O emissions and its microbial driving mechanism, Chemosphere, 267, 129248, doi:10.1016/j.chemosphere.2020.129248; available at *https://pubmed.ncbi.nlm.nih.gov/33321281/.*

[38] Su et al. (2020). Long-term effects of chlorothalonil on microbial denitrification and N_2O emission in a tea field soil, Environmental Science and Pollution Research, 27(14), 17370–17381, doi:10.1007/s11356–020–07679–7; available at *https://link.springer.com/article/10.1007%2Fs11356-020-07679-7.*

[39] 2020 CARB SIP Submittal, Staff Report, 8.

[40] CBD comment, 3.

study.[41] While Almaraz et al. suggest that soil NO_X emissions may be significantly underestimated using currently employed techniques, the study acknowledges the limited number of surface measurements that were available for purposes of comparing the model results and that, where observations exist, there is a large range of observed values due to varying soil conditions (*e.g.,* relating to temperature, moisture, fertilizer application, etc.). The ''top-down'' NO_X emissions estimates derived from aircraft measurements relied upon in the study also reflect a significant degree of uncertainty, reported at 190 tons per day plus or minus 130 tons per day, *i.e.,* plus or minus 68 percent. The authors acknowledge the difficulty in comparing the model results to the observations and note the need for more field measurements.

The challenges associated with quantifying the contribution of fertilizer application to NO_X emissions using currently available datasets are also highlighted in a separate study not cited by the commenter evaluating the impacts of soil NO_X to atmospheric levels of particulate matter in the San Joaquin Valley.[42] In this study, Guo et al. expressed that obtaining an emission factor correlating NO_X emissions to fertilizer application from the data available in various studies (including Almaraz et al.) would be ''difficult or impossible'' due to the sparsity of data collected in terms of, sampling length, sampling frequency, and the episodic nature of nitrogen gases from soil.

Additionally, estimates of the magnitude of agricultural soil NO_X emissions in California vary greatly from study to study. For example, Almaraz et al. estimated that soil NO_X emissions from fertilized croplands account for 32 percent of NO_X emissions across California, Sha et al. estimated soil NO_X emissions to comprise 40.1 percent of California's total NO_X emissions, and Guo et al., estimated that soil NO_X emissions in California equate to only 1.1 percent of anthropogenic NO_X emissions in the State.[43] Similarly, estimates of the fraction of nitrogen applied as fertilizer released as NO_X to the atmosphere was estimated by Almaraz et al. to be 15 percent, while seven other studies reviewed by Guo et al. estimated 2 percent or less.[44] Almaraz et al., Sha et al., and Guo et al. each evaluated the performance of the soil NO_X estimation model used in the respective studies by comparing modeled soil NO_X emissions to observed soil NO_X emission values. Sha et al. and Guo et al. also used photochemical models to compare the resulting predicted NO_2 concentrations to satellite observations of NO_2. Despite producing drastically different estimates of the portion of California's NO_X emissions inventories attributable to soil NO_X, each of these studies report high agreement between modeled and observed soil NO_X emissions.[45] This discrepancy highlights the uncertainty surrounding the available observations, given that agreement between modeled and observed soil NO_X emissions are not sufficient to constrain these disparate model results. Thus, at this time, the EPA does not believe that available research provides sufficient certainty about the magnitude and proportion of soil NO_X emissions attributable to agricultural fertilizer application for the EPA to require that a state categorize these emissions as biogenic or anthropogenic when developing its base year emissions inventories.

While the base year emissions inventories in the 2020 CARB SIP Submittal do not include soil NO_X emissions, the EPA disagrees with the commenter that CARB has assumed the NO_X emissions attributed to soils to be zero. Biogenic emissions (including soil NO_X emissions, if categorized as such) are generally accounted for in the modeled attainment demonstrations submitted for nonattainment areas as recommended in the EPA's ''Modeling Guidance for Demonstrating Air Quality Goals for Ozone, $PM_{2.5}$ and Regional Haze.'' [46] Modeled attainment demonstrations have not yet been submitted to the EPA for California nonattainment areas for the 2015 ozone NAAQS. However, publicly available draft SIP materials for one nonattainment area in California, the Los Angeles-South Coast Air Basin, indicate that soil NO_X emissions have been quantified and will be accounted for in the photochemical modeling relied upon in the area's attainment demonstration.[47] Additionally, CARB has accounted for soil NO_X emissions in modeled attainment demonstrations for recent SIP submittals, including the ''2018 Plan for the 1997, 2006, and 2012 $PM_{2.5}$ Standards'' for the San Joaquin Valley (''2018 SJV $PM_{2.5}$ Plan''),[48] which shows that CARB develops estimates for soil NO_X emissions and will account for these emissions and their impacts on modeled ozone design values in the upcoming attainment plans required for 2015 ozone NAAQS nonattainment areas.

Consistent with applicable emissions inventory requirements and EPA guidance, the EPA generally grants flexibility to states in preparing their base year emissions inventories to comport with the structure and feasibility of their emissions collecting mechanisms, including with respect to the allocation of an emissions source to a particular source category. The requirements for base year emissions inventories in CAA sections 172(c)(3) and 182(a)(1) and at 40 CFR 51.1315 do not include requirements pertaining to the allocation of emissions to source categories, and the EPA's EI Guidance does not suggest whether agricultural soil NO_X emissions should be categorized as an anthropogenic emissions source.[49] The EPA generally

[41] Almaraz et al. (2018).

[42] Guo et al. (2020). Assessment of Nitrogen Oxide Emissions and San Joaquin Valley $PM_{2.5}$ Impacts From Soils in California, Journal of Geophysical Research: Atmospheres, 125(24), doi: 10.1029/2020JD033304; available at *https://doi.org/10.1029/2020JD033304,* 2.

[43] Guo et al. (2020).

[44] Guo et al. (2020), 7, table 2.

[45] For example, in evaluating model performance against satellite-observed NO_2 observations over croplands, Sha et al. reported that the soil NO_X estimation technique employed in the study decreased mean bias by nearly 23% compared to the default model employed by MEGAN version 2.04, concluding that the model employed in the study demonstrated ''good agreement'' with tropospheric NO_2 column observations. Guo et al. validated its soil NO_X model by comparing modeled values to field measurements of soil NO_X flux rates in croplands, finding that ''the model predicted the measured soil NO_X emissions closely, with an r^2 of 0.69 and a p value of <0.001, demonstrating again that the model is capable of reasonably simulating N speciation and emissions from California agricultural ecosystems.''

[46] EPA, ''Modeling Guidance for Demonstrating Air Quality Goals for Ozone, $PM_{2.5}$ and Regional Haze'' (November 2018), section 2.7.7.5.

[47] South Coast Air Quality Management District, 2022 Draft Air Quality Management Plan, Appendix V, V–4–16, V–4–17. Soil NO_X emissions are quantified by running the Model of Emissions of Gases and Aerosols from Nature version 3.0 (MEGAN3.0), which uses the Yienger-Levy model for soil NO_X production. The Yienger-Levy model includes a linear dependence of NO_X emission rates on nitrogen fertilizer application rate for agricultural soils and accounts for NO_X emission pulses observed following the wetting of dry soils. See Yienger, J.J.; Levy, H. Empirical model of global soil-biogenic NO_X emissions. J. Geophys. Res. 1995, 100, 11447–11464.

[48] See the EPA's ''Response to Comments Document for the EPA's Final Action on the San Joaquin Valley Serious Area Plan for the 2006 $PM_{2.5}$ NAAQS'' (June 2020), 149–150. Upon reviewing the 2018 SJV $PM_{2.5}$ Plan, the EPA determined that California used the Model of Emissions of Gases and Aerosols from Nature (MEGAN) and the Model for Ozone and Related chemical Tracers, version 4 (MOZART–4) to generate inputs for photochemical models relied upon in the 2018 SJV Plan. MEGAN and MOZART–4 each include models to estimate soil NO_X emissions. The EPA confirmed with CARB that the photochemical modeling in the 2018 SJV $PM_{2.5}$ Plan accounted for soil NO_X emissions from agricultural sources.

[49] EI Guidance, 100–101. ''Biogenic sources are a subset of natural emissions sources that may

Continued

grants discretion to states to allocate emissions sources to source categories as they deem appropriate for the development of their emissions inventory SIP submittals. Additionally, the EPA's national emissions inventory also does not distinguish naturally occurring soil NO_X emissions from fertilizer-induced soil NO_X emissions, and it categorizes soil NO_X emissions as a biogenic emissions source in name, because emissions are generated from the Biogenic Emissions Inventory System model.[50] [51] Thus, we find it acceptable that CARB did not include soil NO_X emissions as an anthropogenic emissions source in the 2020 CARB SIP Submittal.

With respect to the impact of pesticides on soil NO_X emissions, CBD's comment letter cites numerous studies to suggest that pesticide application increases NO_X emissions from soils. We note that each of these studies correlates pesticide use to nitrous oxide (N_2O) emissions rather than NO_X emissions. These studies include Verhoeven et al. (2017), Spokas and Wang (2003), Jezierska-Tys et al. (2021), XiangZhou et al. (2018), Fang et al. (2021), and Su et al. (2020). These studies do not review pesticide impacts on NO_X emissions, nor do they relate soil N_2O emissions to NO_X emissions. While N_2O is known to contribute to greenhouse climate warming effects and atmospheric ozone depletion, N_2O is not known to be active in the chemical processes contributing to ground-level ozone production and is relatively inert in the troposphere.[52] It is therefore not included in the EPA's definition for NO_X.[53] Because the studies cited by the commenter do not correlate pesticide use (or the resultant N_2O emissions) to NO_X emissions, the EPA disagrees that the information provided by the commenter suggests that CARB's emissions inventories must be modified to include NO_X emissions resulting from pesticide application.

The EPA does not find that CARB assumed NO_X emissions from fertilizers to be zero in its base year emissions inventories. Rather, the EPA understands that CARB included only anthropogenic emissions in its base year inventories and therefore did not include soil NO_X emissions in the base year inventories as a result of considering those emissions to be biogenic. Upon review of applicable statutes and regulations, EPA guidance, studies cited by the commenter, and additional research, the EPA does not find that it must require a particular categorization of soil NO_X emissions in base year emissions inventories at this time. Furthermore, documentation related to various California area SIPs indicates that CARB accounts for NO_X emissions resulting from fertilizer application in its attainment demonstration modeling for nonattainment areas. The studies cited by the commenter related to pesticide application address N_2O emissions rather than NO_X emissions and thus do not indicate that CARB's emissions inventories should be modified to include NO_X emissions resulting from pesticide application. For these reasons, we conclude that the emissions inventories in CARB's submittal do not need to be amended before the EPA may approve them as meeting the applicable base year emissions inventory requirements.

III. Final Action

The comments submitted in response to our proposed action do not change our assessment of the 2020 CARB SIP Submittal as described in our notice of proposed rulemaking. Therefore, for the reasons discussed in detail in the proposed rule and summarized herein, we are finalizing our approval of the 2020 CARB SIP Submittal to address the ozone-related base year emissions inventory requirements for the following 18 ozone nonattainment areas for the 2015 ozone NAAQS in accordance with CAA sections 172(c)(3) and 182(a)(1): Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County.

IV. 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 CAA 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 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 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 an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- 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.

The State did not evaluate environmental justice considerations as part of its SIP submittal. There is no information in the record inconsistent with the stated goals of Executive Order 12898 (59 FR 7629, February 16, 1994) of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

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contribute significantly to an emissions inventory. Vegetation (*i.e.,* forests and agriculture) is the predominant biogenic source of VOC and is typically the only source that is included in a biogenic VOC emissions inventory. Microbial activity in the soil contributes to natural biogenic NO_X and CO emissions.''

[50] See 2017 National Emissions Inventory Technical Support Document (TSD), section 4.4 Agriculture—Fertilizer Application, 4–49—4–56 (January 2021).

[51] The EPA's EI Guidance clarifies that source category groupings relate more to how emissions inventory data are created than to the features of the actual emissions sources included in the category. See EI Guidance, 19. For the purpose of the national emissions inventory, soil NO_X emissions are calculated using the Biogenic Emissions Inventory System, a model that produces estimates of total soil NO_X emissions that are not disaggregated into anthropogenic and biogenic contributions. Thus, the classification of soil NO_X emissions as biogenic in the NEI is a matter of practicality rather than a policy statement.

[52] Seinfeld, J., & Pandis, S. (2016). ''Atmospheric Chemistry and Physics: From Air Pollution to Climate Change,'' John Wiley & Sons, 28.

[53] Per 40 CFR 51.1300, ''Nitrogen Oxides (NO_X) means the sum of nitric oxide and nitrogen dioxide in the flue gas or emission point, collectively expressed as nitrogen dioxide.''

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).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. 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 November 28, 2022. 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, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: September 8, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends 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 paragraph (c)(589) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(589) The following plan was submitted on July 27, 2020 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) California Air Resources Board.

(*1*) California Air Resources Board, ''70 ppb Ozone SIP Submittal,'' excluding section III, ''VMT Offset Demonstration,'' release date: May 22, 2020.

(*2*) [Reserved]

(B) [Reserved]

[FR Doc. 2022–20586 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0480; FRL–9873–02–R9]

Air Plan Disapproval; California; Antelope Valley Air Quality Management District and Mojave Desert Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to disapprove revisions to the Antelope Valley Air Quality Management District (AVAQMD) and the Mojave Desert Air Quality Management District (MDAQMD) portions of the California State Implementation Plan (SIP) concerning rules submitted to address section 185 of the Clean Air Act (CAA or the Act) with respect to the 1-hour ozone standard.

DATES: This rule is effective on October 31, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0480. 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 disabilities 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: Donnique Sherman, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4129 or by email at *sherman.donnique@epa.gov.*

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

Table of Contents

I. Proposed Action

On June 17, 2022 (87 FR 36433), the EPA proposed to disapprove the following rules adopted by the AVAQMD and MDAQMD (collectively, ''the Districts'') that were submitted for incorporation into the California SIP.

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Amended	Submitted
AVAQMD	315	Federal Clean Air Act Section 185 Penalty	10/18/11	12/14/11
MDAQMD	315	Federal Clean Air Act Section 185 Penalty	10/24/11	12/14/11

We proposed to disapprove these rules because some rule provisions do not satisfy the requirements of section 110 and part D of the Act. These provisions include the following:

1. AVAQMD Rule 315 refers to the term ''Major Facility'' as defined in ''District Rule 1301.'' The current SIP-approved Rule 1301 for AVAQMD does not contain a definition of ''Major Facility.''

2. The Districts did not provide a justification for the method chosen to calculate alternate baseline emissions for facilities with emissions that are irregular, cyclical, or otherwise vary significantly, which differs from the method EPA has previously considered to be generally approvable as explained in the EPA's guidance.

3. The rules establish an area-wide equivalency ''Tracking Account.'' This system requires the cooperation and coordination of three districts: AVAQMD, MDAQMD, and the South Coast Air Quality Management District (SCAQMD). Each rule requires the respective Air Pollution Control Officer (APCO) to request an accounting from the other Districts, but there is no requirement for the APCO to provide their accounting to the other Districts. The rules assume accounting across the three Districts with the same system in place. SCAQMD does not have a rule that contains the same provisions. As a result, the area-wide accounting system is not enforceable.

4. The formula for calculating the penalty fee needs correcting to properly reflect the inflation adjustment based on the Consumer Price index.

Our proposed action and technical support document (TSD) contain more information on the basis for this disapproval and on our evaluation of the submitted rules.

II. Public Comments and the EPA's Responses

The EPA's proposed action provided a 30-day public comment period. During the comment period we received one comment from the MDAQMD, and one comment from the AVAQMD.

Comment 1: AVAQMD commented that, ''the current SIP version of the AVAQMD New Source Review (NSR) Regulations are those approved for SCAQMD on December 4, 1996. Of those SIP approved rules, Rule 1302 contains applicable definitions including the term 'Major Polluting Facility.' The AVAQMD and its predecessor agencies has amended and caused to be submitted to USEPA these rules on several occasions with a shift of the definitions to Rule 1301 and a slight change in terminology to 'Major Facility.' To avoid confusion on the part of regulated facilities, cross references need to be to the current rule book rules. Thus, the deficiency as noted in the TSD in Section 4.b.1. is not only unavoidable but a direct result of USEPA's inaction on prior submissions. As USEPA indicates in the TSD this deficiency will be resolved whenever USEPA acts upon the most current NSR submission.''

Response 1: As indicated in our TSD associated with our proposed action, we anticipate that approval of the current locally adopted versions of AVAQMD Rule 1301 and AVAQMD Rule 1303 into the SIP will resolve this deficiency. The AVAQMD's comment does not appear to challenge our proposed action and therefore does not impact our proposed disapproval.

Comment 2: The Districts both commented that it would be helpful if the EPA could ''indicate a potential timeline for action on [their other section 185 penalty] rules.'' They further mentioned that this would enable the Districts ''to either amend Rule 315 quickly so that it can be evaluated with the other FCAA 185 penalty rules or to wait for EPA to expeditiously identify deficiencies in those other rules'' so they can adjust Rule 315 appropriately.

Response 2: The CAA outlines the EPA's review process, deadlines, and timeframes. CAA section 110(k)(2) states that once a submitted plan or plan revision is determined complete, the EPA shall act on the submission within 12 months of that determination. We understand that the Districts would like to streamline their rulemaking efforts. We will make every effort to keep the Districts informed of the status of submitted SIP revisions in consideration of local district rulemaking timelines.

Comment 3: The Districts both commented that: ''While the Southeast Desert Modified AQMD was found to have failed to attain the old 1-hour O_3 standard based on 2005–2007 data in 2011 it must be noted that the area subsequently attained the standard as early as the 2009–2011 data set. In fact, USEPA noted that such attainment was possible based on the preliminary review of the 2010–2012 data set in its Notice of Proposed Rulemaking Determination of Attainment of the 1-Hour Ozone National Ambient Air Quality Standard in the Southeast Desert Nonattainment Area in California on August 25, 2014. This attainment determination was finalized on April 15, 2015. Due to the timing of the Rule adoption, USEPA's actions and the subsequent attainment designation the [AVAQMD/MDAQMD] asserts that the provisions of Rule 315 have not been triggered and are unlikely to be triggered in the future as the 1-hour O_3 standard has been fully rescinded.''

Response 3: The EPA does not agree with the Districts' statement that the provisions of Rule 315 have not been triggered and are unlikely to be triggered in the future. To the extent that this comment is based on the requirement to have a section 185 program for a revoked national ambient air quality standard (NAAQS), the Districts are incorrect. To the extent that it is based on the text of the rules themselves, the EPA does not find support in the text of the rules for the proposition that the rules require a trigger to become effective.

As the commenters note, the EPA found that the Southeast Desert Modified Air Quality Management Area (AQMA) failed to attain the now-revoked 1-hour ozone standard based on 2005–2007 data in 2011.[1] In that action, we explained that although the EPA revoked the 1-hour ozone standard, to comply with anti-backsliding requirements of the Act, 8-hour ozone nonattainment areas remain subject to certain requirements based on their 1-hour ozone classification. Initially, in our rules to address the transition from the 1-hour to the 8-hour ozone standard, the EPA did not include the section 185 fee program among the measures retained as 1-hour ozone anti-backsliding requirements.[2] However, on December 23, 2006, the United States Court of Appeals for the District of Columbia Circuit determined that the EPA should not have excluded these requirements (and certain others not relevant here) from its anti-backsliding requirements.[3] As a result, the section 185 major source fee program is maintained as an anti-backsliding measure for the 1-hour ozone NAAQS in areas that were classified as Severe or Extreme nonattainment for the 1-hour standard at the time of revocation.

In our 2011 notice finding that the Southeast Desert Modified AQMA failed to attain the 1-hour ozone NAAQS, the EPA explained, citing the *South Coast* decision, that the rationale for the finding was that ''after revocation of the one-hour ozone standard, the EPA must continue to provide a mechanism to give effect to the one-hour anti-backsliding requirements that have been

[1] 76 FR 82133 (December 30, 2011).

[2] 69 FR 23951 (April 30, 2004).

[3] *South Coast Air Quality Management District* v. *EPA,* 472 F.3d 882 (D.C. Cir. 2006) reh'g denied 489 F.3d 1245 (clarifying that the vacatur was limited to the issues on which the court granted the petitions for review) (referred to herein as the *South Coast* case).

specifically retained'' and that our finding was ''in keeping with this responsibility with respect to one-hour anti-backsliding . . . section 185 fee programs.'' [4] Specifically, we wrote that a consequence of the finding of failure to attain by the attainment date was ''to give effect to the section 185 fee requirements to the extent they are not already in effect'' within the nonattainment areas covered by the finding, including the Southeast Desert Modified AQMA.[5] Accordingly, the districts within the Southeast Desert Modified AQMA are required to comply with the section 185 fee program requirements.

The Districts note that ''the area subsequently attained the standard as early as the 2009–2011 data set'' and that ''USEPA noted that such attainment was possible based on the preliminary review of the 2010–2012 data set,'' citing our August 25, 2014 proposal [6] and April 15, 2015 final [7] rules titled ''Determination of Attainment of the 1-Hour Ozone National Ambient Air Quality Standard in the Southeast Desert Nonattainment Area in California.'' The EPA's determination that the area attained the standard based on the 2009–2011 data set is a type of action commonly known as a Clean Data Determination (CDD). The CDD does not impact the Districts' section 185 obligations. Section 185 of the CAA states that this obligation applies to areas that fail to attain an ozone NAAQS by the relevant attainment date. Specifically, section 185 states, ''[e]ach implementation plan revision required under section 7511a(d) and (e) of this title (relating to the attainment plan for Severe and Extreme ozone nonattainment areas) shall provide that, if the area to which such plan revision applies has failed to attain the national primary ambient air quality standard for ozone *by the applicable attainment date*'' major stationary sources in the nonattainment area must pay section 185 fees (emphasis added). As discussed above, the EPA has determined that the Southeast Desert Modified AQMA failed to attain the 1-hour ozone standard by the November 15, 2007, applicable attainment date.[8]

Furthermore, section 185 of the Act does not provide relief from fees in the event the EPA subsequently issues a CDD. Section 185 specifically provides that such fees must be paid ''until the area is redesignated as an attainment area for ozone.'' A Clean Data Determination is not the same as a redesignation to attainment.[9] While the statute specifies that redesignation to attainment will remove the requirement for an area to implement the section 185 fee requirement, a CDD does not.[10] Accordingly, our 2015 Determination of Attainment for the area did not turn off the section 185 obligation, and that requirement remains active in the Southeast Desert Modified AQMA.

To the extent that the Districts' assertion that ''the provisions of Rule 315 have not been triggered and are unlikely to be triggered in the future'' is based on the text of the rules themselves, the EPA does not see a basis for this claim. If the Districts' comments are meant to suggest that AVAQMD Rule 315 and MDAQMD Rule 315 have not become effective or require an event to trigger them in the future, the EPA does not agree. Rule 315 does not contain any provisions that indicate that a triggering event is required for them to become effective. Rule 315 ''is applicable to any Facility within the District Portion of the AQMA which emits or has the potential to emit nitrogen oxides (NO_X) or Volatile Organic Compounds (VOC) in an amount sufficient to make it a Major Facility'' and ''cease[s] to be applicable when the AQMA is designated as attaining the one-hour national ambient air quality standard for ozone.'' As discussed above, the area has not been redesignated as attaining the 1-hour ozone NAAQS. No exemption or other provision of the rule suggests that the rule is not applicable or that the rule must be ''triggered'' in any way. Accordingly, the EPA does not agree with this aspect of the Districts' comments.

The Districts' suggestions that the rules require a triggering event in order to become effective do not impact our proposed disapproval because the EPA is proposing to disapprove AVAQMD Rule 315 and MDAQMD Rule 315 on other grounds. The EPA notes that any rule that may be submitted to address the deficiencies identified in this rulemaking should not include a future event to trigger applicability because the attainment date has already passed and the area has failed to attain.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action and the associated TSD. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is finalizing a disapproval of submitted AVAQMD Rule 315 and MDAQMD Rule 315. As a result, the offset sanction in CAA section 179(b)(2) will be imposed 18 months after the effective date this action, and the highway funding sanction in CAA section 179(b)(1) six months after the offset sanction is imposed. A sanction will not be imposed if the EPA determines that a subsequent SIP submission corrects the identified deficiencies before the applicable deadline. In addition to the sanctions, CAA section 110(c) provides that the EPA must promulgate a federal implementation plan (FIP) addressing any disapproved elements of the SIP within two years after the effective date of the disapproval unless we approve subsequent SIP revisions that correct the rule deficiencies. As a result of the EPA's January 5, 2010 determination that California had failed to submit the required CAA section 185 fee programs for the 1-hour ozone NAAQS for certain nonattainment areas (75 FR 232), the EPA is already subject to a statutory deadline to promulgate a FIP for this purpose. Note that the submitted rules were adopted by AVAQMD and MDAQMD, and the EPA's final disapproval does not prevent the local agencies from enforcing them.

IV. 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.*

[4] 76 FR 82133, 82135.

[5] Id. at 82136.

[6] 79 FR 50574.

[7] 80 FR 20166.

[8] 76 FR 82133.

[9] In order to be redesignated to attainment, the Act requires that: (1) an area attain the relevant NAAQS, (2) the area have a fully approved attainment plan, (3) the Administrator determine that improvement in air quality is due to permanent and enforceable reductions in emissions, (4) the area have a fully approved maintenance plan, and (5) the State meet all applicable requirements for the area under section 110 and Part D of the Act. CAA § 107(d)(2)(E).

[10] See 40 CFR 51.918, specifying that a determination that an ozone nonattainment area has attained a NAAQS suspends certain requirements, not including the section 185 fee obligation, and that a subsequent redesignation to attainment would terminate these requirements. See also Memorandum from John D. Seitz, ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' May 10, 1995 (''Determinations made by EPA that an area has attained the NAAQS . . . is not equivalent to the redesignation of the area to attainment.''); 40 CFR 51.1105, describing the ''redesignation substitute'' procedure that allows areas that were designated nonattainment for a revoked NAAQS at the time of revocation to turn off the anti-backsliding requirements (a petition for review regarding this provision is currently pending before the Court of Appeals for the District of Columbia in *Sierra Club* v. *EPA,* Case #20–1121).

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA, because this SIP disapproval does not in-and-of itself create any new information collection burdens, but simply disapproves certain state requirements for inclusion in the SIP.

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. This SIP disapproval does not in-and-of itself create any new requirements but simply disapproves certain state requirements for inclusion in the SIP.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action disapproves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

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: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP revision that the EPA is disapproving would not 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, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because this SIP disapproval does not in-and-of itself create any new regulations, but simply disapproves certain state requirements for inclusion in the SIP.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The state did not evaluate environmental justice considerations as part of its SIP submittal. There is no information in the record inconsistent with the stated goals of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

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).

L. Petitions for Judicial Review

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 November 28, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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: September 21, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended 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 52.237 is amended by adding paragraph (c) to read as follows:

§ 52.237 Part D disapproval.

* * * * *

(c) The following Clean Air Act section 185 fee rules, and the section 185 program plan element for the specified NAAQS, are disapproved because they do not meet the requirements of Part D of the Clean Air Act.

(1) Antelope Valley Air Quality Management District.

(i) Rule 315, ''Federal Clean Air Act Section 185 Penalty,'' amended on October 18, 2011, and submitted on December 14, 2011, for the 1979 1-hour ozone NAAQS.

(ii) [Reserved]

(2) Mojave Desert Air Quality Management District.

(i) Rule 315, ''Federal Clean Air Act Section 185 Penalty,'' amended on October 24, 2011, and submitted on December 14, 2011, for the 1979 1-hour ozone NAAQS.

(ii) [Reserved]

[FR Doc. 2022–20858 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0417; FRL–10088–01–OCSPP]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet, subgroup 1B. Syngenta requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 29, 2022. Objections and requests for hearings must be received on or before November 28, 2022 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0417, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0417 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before November 28, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0417, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 22, 2021 (86 FR 52624) (FRL–8792–03–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8914) by Syngenta Crop Protection, LLC. The petition requested that 40 CFR 180.686 be amended by establishing tolerances for residues of the fungicide benzovindiflupyr, in or on vegetable, root, except sugar beet, subgroup 1B, and ginseng, at 0.6 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket ID number EPA–HQ–OPP–2021–0417 at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified a commodity definition, established the tolerance at an increased level, and removed the existing ginseng tolerance. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for benzovindiflupyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with benzovindiflupyr follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for benzovindiflupyr, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to benzovindiflupyr and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological profile of benzovindiflupyr, see Unit III.A. of the June 22, 2018, rulemaking (83 FR 29033) (FRL–9977–94).

Toxicological points of departure/Levels of concern. For a summary of the toxicological points of departure/levels of concern used for the safety assessment, see Unit III.B. of the October 2, 2015, rulemaking (80 FR 59627) (FRL–9933–03).

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the June 22, 2018, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of benzovindiflupyr on the commodities in Vegetable, root, except sugar beet, subgroup1B. The assessments used the same assumptions considering 100 percent crop treated and tolerance-level residues as the June 22, 2018, final rule. Drinking water exposures are not impacted by the new uses; the estimated drinking water concentrations are the same as in the June 22, 2018, final rule.

The proposed new use will not result in residential exposure, although there are existing residential uses that were previously assessed. The revisions to the residential exposure and risk assessments in the June 22, 2018, final rule were described in the February 9, 2021, final rule (86 FR 8704) (FRL–10017–32) and have not changed since then.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to benzovindiflupyr and any other substances and benzovindiflupyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that benzovindiflupyr has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the June 22, 2018, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and Determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD: They are 16% of the aPAD for the general population and 43% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: They are 6.1% of the cPAD for the general population and 20% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Because the chronic dietary risks, which were quantified using a non-linear (*i.e.,* RfD) approach accounting for all chronic toxicity and any potential carcinogenic effects, are below EPA's level of concern, the Agency concludes that benzovindiflupyr will not pose a cancer risk. The short-term aggregate MOE (food, water, and residential) is 487 for children 1 to 2 years old. This MOE exceeds the target level of concern of 100, so it is not of concern. There are no intermediate or long-term residential exposures.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to benzovindiflupyr residues. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the documents titled ''Benzovindiflupyr. Human Health Risk Assessment for the Proposed New Food Use on Vegetable Root, Subgroup 1B (except sugar beets)'' in docket ID number EPA–HQ–OPP–2021–0417.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the June 22, 2018, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex has not established an MRL for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet, subgroup 1B.

C. Revisions to Petitioned-For Tolerances

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. EPA is establishing the tolerance at 0.6 ppm for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet,

subgroup 1B. The EPA determined a higher tolerance was required by calculating the recommended tolerance for carrot and radish data separately and using the highest recommended tolerance rather than calculating the recommended tolerance using the combined carrot and radish data as the registrant did. The Agency also revised the commodity definition to use standard terminology for the subgroup.

Additionally, the petition requested that ginseng be excluded from the tolerance for subgroup 1B. However, rather than exclude ginseng from this tolerance to avoid duplicative tolerances, EPA is removing the established tolerance of 0.3 ppm for residues of benzovindiflupyr in or on ginseng because it is included in the crop subgroup covered by this tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of benzovindiflupyr, in or on vegetable, root, except sugar beet, subgroup 1B at 0.6 ppm. In addition, EPA is removing the established tolerance for residues of benzovindiflupyr in or on ginseng at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.686, amend the table 1 to paragraph (a) by:
■ a. Removing the entry for ''Ginseng''; and
■ b. Adding in alphabetical order an entry ''Vegetable, root, except sugar beet, subgroup 1B''.

The addition reads as follows:

§ 180.686 Benzovindiflupyr; tolerances for residues

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	0.6
* * * * *	

* * * * *

[FR Doc. 2022–21159 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

Standards for the Electronic Health Record Technology Incentive Program

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 42 of the Code of Federal Regulations, Parts 482 to End, revised as of October 1, 2021, revise § 495.22(e)(8)(i)(A)(*2*)(*ii*) to read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2018.

* * * * *

(e) * * *
(8) * * *
(i) * * *
(A) * * *
(*2*) * * *

(*ii*) In 2017 and 2018, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period.

* * * * *

[FR Doc. 2022–21193 Filed 9–28–22; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 203 and 252

[Docket DARS–2022–0001]

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule; technical amendment.

SUMMARY: DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) in order to make needed editorial changes.

DATES: Effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, Defense Acquisition Regulations System, telephone 703–717–8226.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS to make needed editorial changes to 48 CFR parts 203 and 252.

List of Subjects in 48 CFR Parts 203 and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 203 and 252 are amended as follows:

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 1. The authority citation for 48 CFR part 203 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

203.171–1 [Amended]

■ 2. Amend section 203.171–1 by removing ''Section'' and ''Public Law'' and adding ''section'' and ''Pub. L.'' in their places, respectively.

203.171–3 [Amended]

■ 3. Amend section 203.171–3 in paragraph (a) by removing ''Section'' and adding ''section'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRCT CLAUSES

■ 4. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 5. Amend section 252.239–7010 by:

■ a. Revising the section heading and the clause date; and

■ b. Removing fromm paragraph (b)(2) ''*http://iase.disa.mil/cloud_security/Pages/index.aspx unless notified by the Contracting Officer that this requirement has been waived by the DoD Chief Information Officer.*'' and adding ''*https://public.cyber.mil/dccs/dccs-documents/* unless notified by the Contracting Officer that this requirement has been waived by the DoD Chief Information Officer.'' in its place.

The revisions read as follows:

252.239–7010 Cloud Computing Services.

* * * * *

Cloud Computing Services (Sep 2022)

* * * * *

[FR Doc. 2022–20966 Filed 9–28–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2022–0022]

RIN 0750–AL52

Defense Federal Acquisition Regulation Supplement: Representation Relating to Compensation of Former DoD Officials (DFARS Case 2021–D030)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify the requirement for offerors to represent whether former DoD officials employed by the offeror are in compliance with post-employment restrictions.

DATES: Effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Monica Wideman, telephone 703–717–3446.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is issuing a final rule to implement a recommendation of the Government Accountability Office (GAO). Section 851 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2007 (Pub. L. 109–364) required GAO to report on recent employment of former DoD officials by major defense contractors. In May 2008, GAO issued a report titled ''Defense Contracting: Post-Government Employment of Former DoD Officials Needs Greater Transparency (GAO–08–485).'' GAO concluded that greater transparency was needed by DoD with respect to former senior and acquisition executives (*i.e.,* DoD ''covered officials'') to ensure compliance with applicable post-employment restrictions.

Subsequently, DoD issued a final rule in the **Federal Register** at 76 FR 71826, effective November 18, 2011, which implemented the GAO recommendation by adding a new representation for offerors to complete and provide as part of each proposal, including proposals for commercial items. The representation is required only one time rather than continuously throughout contract performance. The solicitation provision at DFARS 252.203–7005, Representation Relating to Compensation of Former DoD Officials, is a representation that all of the offeror's employees who are former DoD officials are in compliance with all post-employment restrictions at 18 U.S.C. 207, 41 U.S.C. 2101–2107, and 5 CFR parts 2637 and 2641, as well as Federal Acquisition Regulation (FAR) 3.104–2.

A more recent GAO Report titled ''GAO–21–104311, Post-Government Employment Restrictions-DoD Could Further Enhance Its Compliance Efforts Related to Former Employees Working for Defense Contractors,'' dated September 9, 2021, states that in 2011 DoD modified its acquisition regulations to require that contractors, when submitting proposals in response to DoD solicitations, represent their employees' compliance with several post-Government employment restrictions. Although GAO recognized that DoD has provided guidance on section 1045 of the NDAA for FY 2018 (Pub. L. 115–91), to include DoD Instruction 1000.32, ''Prohibition of Lobbying Activity by Former DoD Senior Officials,'' the GAO report pointed out that DoD has not added section 1045 of the NDAA for FY 2018 to the list of post-Government

employment ethics provisions currently enumerated within the solicitation provision at DFARS 252.203–7005. Specifically, since section 1045, which restricts lobbying activities with respect to DoD matters by former DoD senior officials, was enacted after the addition of DFARS 252.203–7005 in 2011, it was not originally included in the list of enumerated post-Government employment provisions. Therefore, GAO recommended that DoD assess whether to amend the DFARS to add section 1045 to the required offeror representation concerning compliance with post-Government employment restrictions.

This final rule revises DFARS provision 252.203–7005, Representation Relating to Compensation of Former DoD Officials, to add the statutory reference to section 1045 of the NDAA for FY 2018 to the existing list of post-Government employment restrictions to ensure that, to the extent the individuals are ''covered DoD officials'' under the definition at DFARS 252.203–7000, the lobbying activities restrictions contained in section 1045 are included among the enumerated post-Government employment ethics provisions. Additionally, the provision language was revised to clarify that former personnel are required to comply with all applicable post-Government employment restrictions, not just those enumerated in the solicitation provision at DFARS 252.203–7005.

An obsolete reference to 5 CFR 2637 is removed from the provision. Part 2637 was removed from title 5 of the CFR in a final rule published in the **Federal Register** at 73 FR 36168 (June 25, 2008).

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the FAR is 41 U.S.C. 1707, Publication of Proposed Regulations. Subsection (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors.

Under the existing DFARS requirement, offerors must represent that their employees subject to section 847 of the NDAA for FY 2008 are in compliance with applicable post-Government employment restrictions, which are outlined in the written post-Government employment opinion letter issued pursuant to section 847. Following the enactment of section 1045 of the NDAA for FY 2018, DoD included the requirement in DoD Instruction 1000.32, Prohibition of Lobbying Activity by Former DoD Senior Officials, that post-Government employment opinions address section 1045, where applicable. Therefore, this final rule is not required to be published for public comment, because it does not constitute a significant DFARS revision within the meaning of FAR 1.501–1 and does not have a significant cost or administrative impact on contractors or offerors (see Section I of this preamble).

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services and Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

This rule amends the solicitation provision at DFARS 252.203–7005. However, this rule does not impose any new requirements on contracts at or below the SAT or for commercial services or commercial products, including COTS items. The provision will continue to apply to acquisitions at or below the SAT and to acquisitions of commercial services and commercial products, including COTS items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

VII. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 252.203–7005 by—

■ a. Revising the provision date;

■ b. Revising paragraph (b); and

■ c. Adding ''(End of provision)'' at the end of the provision.

The addition and revisions read as follows:

252.203–7000 Representation Relating to Compensation of Former DoD Officials.

* * * * *

Representation Relating to Compensation of Former DOD Officials (Sep 2022)

* * * * *

(b) By submission of this offer, the Offeror represents, to the best of its knowledge and belief, that all covered DoD officials employed by or otherwise receiving compensation from the Offeror, and who are expected to undertake activities on behalf of the Offeror for any resulting contract, are presently in compliance with all applicable post-employment restrictions, including those contained in 18 U.S.C. 207, 41 U.S.C. 2101–2107, 5 CFR part 2641, section 1045 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91), and Federal Acquisition Regulation 3.104–2.

(End of provision)

[FR Doc. 2022–20965 Filed 9–28–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 350, 360, 380, 382, 383, 385, 391, 395, 396, and 397

[Docket No. FMCSA–2022–0149]

RIN 2126–AC47

General Technical, Organizational, Conforming, and Correcting Amendments to the Federal Motor Carrier Safety Regulations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA amends its regulations by making technical corrections throughout the Federal Motor Carrier Safety Regulations (FMCSRs). The Agency makes minor changes to correct inadvertent errors and omissions, remove or update obsolete references, and improve the clarity and consistency of certain regulatory provisions. The Agency also makes nondiscretionary, ministerial changes that merely align regulatory requirements with the underlying statutory authority, including the Infrastructure Improvement and Jobs Act (IIJA), sometimes referred to as the Bipartisan Infrastructure Law, requirements. Additionally, the Agency makes changes relating to agency management and to FMCSA's rules of organization, procedures, or practice.

DATES: This final rule is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Nicholas Warren, Regulatory Development Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–6124; *nicholas.warren@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Legal Basis for the Rulemaking

Congress delegated certain powers to regulate interstate commerce to the United States Department of Transportation (DOT or Department) in numerous pieces of legislation, most notably in section 6 of the Department of Transportation Act (DOT Act) (Pub. L. 89–670, 80 Stat. 931, 937, Oct. 15, 1966). Section 6 of the DOT Act transferred to the Department the authority of the former Interstate Commerce Commission (ICC) to regulate the qualifications and maximum hours of service of employees, the safety of operations, and the equipment of motor carriers in interstate commerce (80 Stat. 939). This authority, first granted to the ICC in the Motor Carrier Act of 1935 (Pub. L. 74–255, 49 Stat. 543, Aug. 9, 1935), now appears in 49 U.S.C. chapter 315. The regulations issued under this (and subsequently enacted) authority became known as the FMCSRs, codified at 49 CFR parts 350–399. The administrative powers to enforce chapter 315 (codified in 49 U.S.C. chapter 5) were also transferred from the ICC to the DOT in 1966, assigned first to the Federal Highway Administration (FHWA), and then to FMCSA. The FMCSA Administrator, whose powers and duties are set forth in 49 U.S.C. 113, has been delegated authority by the Secretary of Transportation (the Secretary) under 49 CFR 1.81 to prescribe regulations and to exercise authority over and with respect to any personnel within the organization, and under 49 CFR 1.87 to carry out the motor carrier functions vested in the Secretary.

Between 1984 and 1999, enforcement of the FMCSRs, the Hazardous Materials Regulations, and the Commercial Regulations were added to FHWA's authority. These statutes include the Motor Carrier Safety Act of 1984 (Pub. L. 98–554, Title II, 98 Stat. 2832, Oct. 30, 1984), codified at 49 U.S.C. chapter 311, subchapter III; the Commercial Motor Vehicle Safety Act of 1986 (Pub. L. 99–570, Title XII, 100 Stat. 3207–170, Oct. 27, 1986), codified at 49 U.S.C. chapter 313; the Hazardous Materials Transportation Uniform Safety Act of 1990, as amended (Pub. L. 101–615, 104 Stat. 3244, Nov. 16, 1990), codified at 49 U.S.C. chapter 51; the Omnibus Transportation Employee Testing Act of 1991 (Pub. L. 102–143, Title V, 105 Stat. 917, 952, Oct. 28, 1991), codified at 49 U.S.C. 31306; the ICC Termination Act of 1995 (Pub. L. 104–88, 109 Stat. 803, Dec. 29, 1995), codified at 49 U.S.C. chapters 131–149; and the Transportation Equity Act for the 21st Century (Pub. L. 105– 178, 112 Stat. 107, June 9, 1998).

The Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L. 106–159, 113 Stat. 1748, Dec. 9, 1999) established FMCSA as a new operating administration within DOT, effective January 1, 2000. Accordingly, since that time the motor carrier safety, and certain commercial, responsibilities previously assigned to both the ICC and FHWA are the jurisdiction of FMCSA.

Congress expanded, modified, and amended FMCSA's authority in the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (Pub. L. 107–56, 115 Stat. 272, Oct. 26, 2001); the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59, 119 Stat. 1144, Aug. 10, 2005); the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572, June 6, 2008); the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, 126 Stat. 405, July 6, 2012); and the Fixing America's Surface Transportation Act (Pub. L. 114–94, 129 Stat. 1312, Dec. 4, 2015). Most recently, Congress amended FMCSA's authorities in the Infrastructure Improvement and Jobs Act (IIJA) (Pub. L. 117– 58, 135 Stat. 429, Nov. 15, 2021). Accordingly, FMCSA amends three parts in title 49 of the Code of Federal Regulations (CFR) to align the regulatory text with the new statutory requirements.

The specific regulations amended by this rule are based on the statutes detailed above. Generally, the legal authority for each of those provisions was explained when the requirement was originally adopted and is noted at the beginning of each part in title 49 of the CFR.

The Administrative Procedure Act (APA) specifically provides exceptions to its notice and comment rulemaking procedures when an agency finds there is good cause to dispense with them, and incorporates the finding, and a brief statement of reasons therefore, in the rules issued (5 U.S.C. 553(b)(3)(B)). Good cause exists when an agency determines that notice and public comment procedures are impractical, unnecessary, or contrary to the public interest. The amendments made in this final rule primarily correct inadvertent errors and omissions, remove or update obsolete references, and make minor language changes to improve clarity and consistency. Some changes are statutorily mandated or align regulatory standards with the underlying statutory authority. In accommodating those changes, the Agency is performing nondiscretionary, ministerial acts. The technical amendments do not impose any material new requirements or increase compliance obligations. For these reasons, FMCSA finds good cause that notice and public comment on this final rule are unnecessary.

Moreover, the amendments changing the name of the ''Office of Enforcement and Compliance (MC–EC)'' to the ''Office of Enforcement and Compliance (MC–SE)'' and ''Office of Safety

Programs (MC–SS)'' and additional methods for the public to contact certain Agency offices concern an additional exception to the APA's notice and comment rulemaking procedures for ''rules of agency organization, procedure, or practice'' (5 U.S.C. 553(b)(3)(A)). These amendments are, therefore, excepted from the notice and public comment requirements.

The APA also allows agencies to make rules effective immediately with good cause (5 U.S.C. 553(d)(3)), instead of § requiring publication 30 days prior to the effective date. For the reasons already stated, FMCSA finds there is good cause for this rule to be effective immediately.

The Agency is aware of the regulatory requirements concerning public participation in FMCSA rulemaking (49 U.S.C. 31136(g)). These requirements pertain to certain major rules,[1] but, because this final rule is not a major rule, they are not applicable.

II. Section-by-Section Analysis

This section-by-section analysis describes the changes to the regulatory text in numerical order.

A. Part 350—Motor Carrier Safety Assistance Program (MCSAP) and High Priority Program

Section 350.221 How long are MCSAP funds available to a State?

Section 23001(b)(4)(A) of IIJA amends 49 U.S.C. 31104(f)(1) to provide that MCSAP funds are available for the Federal fiscal year that the funds are obligated and for the next 2 fiscal years, instead of just the next fiscal year. Accordingly, FMCSA amends § 350.221 by replacing ''next full Federal fiscal year'' with ''next 2 full Federal fiscal years.''

Section 350.227 What activities are eligible for reimbursement under MCSAP?

Section 23001(c) of IIJA amends 49 U.S.C. 31102(h)(2)(A) to provide that MCSAP funds may be used for documented enforcement of State traffic laws and regulations if, in part, the number of motor carrier safety activities conducted in the State is maintained at a level at least equal to the average level of such activities conducted in the State in fiscal years 2014 and 2015, instead of 2004 and 2005. Accordingly, FMCSA amends § 350.227(c)(2)(ii) by replacing ''2004 and 2005'' with ''2014 and 2015.''

Section 350.403 What are the High Priority Program objectives?

Section 23003 of IIJA amends 49 U.S.C. 31102(l)(3)(D) by adding a new clause (iv) and clause (v), which provide that High Priority Program funds received to advance the innovative technology deployment of commercial motor vehicle (CMV) information systems and networks may also be used to combat human trafficking. Accordingly, FMCSA adds a clause at the end of paragraph (h) in § 350.403 pertaining to innovative technology deployment that reads, ''including technology to detect, and enforce actions taken as a result of, criminal activity (including human trafficking) in a CMV or by any occupant of a CMV, including the operator.''

Similarly, section 23003 of IIJA amends 49 U.S.C. 31102(l)(2) by adding new subparagraphs (H) and (I), which provide that High Priority Program funds may be used to combat human trafficking. Accordingly, FMCSA adds a new paragraph (j) in § 350.403 that provides High Priority Program funds may be used to ''Support the recognition, prevention, and reporting of human trafficking in a CMV or by any occupant of a CMV, including the operator, and enforce laws relating to human trafficking; or.'' FMCSA makes conforming changes by deleting ''or'' at the end of paragraph (i) and redesignating the existing paragraph (j) as (k).

Section 350.405 What conditions must an applicant meet to qualify for High Priority Program funds?

In paragraph (a) of § 350.405, FMCSA makes conforming changes to reflect the addition of a paragraph in § 350.403. Specifically, FMCSA replaces '', (i), and (j)'' with ''and (i) through (k).''

Section 350.411 How long are High Priority Program funds available to a recipient?

As above, in paragraph (a) of § 350.411, FMCSA makes conforming changes to reflect the addition of a paragraph in § 350.403. FMCSA replaces '', (i), and (j)'' with ''and (i) through (k).''

B. Part 360—Fees for Motor Carrier Registration and Insurance

Sections 360.3 (Suspended) and 360.3T Filing fees. [2]

FMCSA revises paragraph (e)(3)(iii) of § 360.3(suspended) and paragraph (e)(2)(iii) of § 360.3T to replace ''Director, Office of Registration and Safety Information (MC–RS)'' with ''Federal Motor Carrier Safety Administration.'' This change is consistent with similar changes made in the final rule titled ''General Technical, Organizational, Conforming, and Correcting Amendments to the Federal Motor Carrier Safety Regulations'' (86 FR 57060, Oct. 14, 2021). FMCSA made changes in that final rule to replace specific employees and offices in the FMCSRs noting recent vacancies and organizational changes affected the titles of FMCSA employees and office names, which underscored the need for increased flexibility to redelegate functions internally to meet organizational needs. Accordingly, FMCSA simplified many sections across various parts of the CFR removing or updating references to specific titles or offices and replaced them with ''FMCSA'' and, where necessary, an ''ATTN'' line showing the subject matter of the petition or request. (See 86 FR 57061). FMCSA inadvertently omitted §§ 360.3(e)(3)(iii) and 360.3T(e)(2)(iii) from the list of sections that were amended under this rationale. FMCSA corrects that omission and amends these sections to be consistent with similar sections of the FMCSRs.

Part 380—Special Training Requirements

Section 380.703 Requirements for Listing on the Training Provider Registry (TPR)

FMCSA revises paragraphs (a)(7) and (b) by replacing the words ''website'' with the word ''website.''

Section 380.717 Training Certification

FMCSA revises the introductory text to § 380.717 by replacing the words ''website'' with the word ''website.''

Section 380.723 Removal From Training Provider Registry: Procedure

FMCSA revises paragraph (a) by adding ''or through the TPR website'' to

[1] A ''major rule'' means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, Federal agencies, State agencies, local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 804(2)).

[2] On January 17, 2017, FMCSA suspended certain regulations relating to the electronic Unified Registration System and delayed their effective date indefinitely (82 FR 5292). The suspended regulations were replaced by temporary provisions that contain the requirements in place on January 13, 2017. Section 360.3 was one of the sections suspended and § 360.3T, which is currently in effect, was one of the replacement sections added (82 FR 5299).

the end of the first sentence. This revision reflects that removal from the training provider registry may be accomplished by submitting a notice through the same ''TPR website'' that is used for other transmittals of documents regarding the registry in part 380. Additionally, in paragraph (b), FMCSA replaces the words ''website'' with the word ''website.''

C. Part 382—Controlled Substances and Alcohol Use and Testing

Section 382.119 Stand-Down Waiver Provision

FMCSA revises paragraph (e) to replace ''Office of Enforcement and Compliance (MC–EC)'' with ''Office of Safety Programs (MC–SS).'' This change aligns regulatory text with updates to the internal organization of FMCSA and ensures that written requests submitted under this section are directed to the correct office within the Agency.

Section 382.303 Post-Accident Testing

FMCSA replaces ''Federal, State, or local official having independent authority to test'' with ''Federal, State, or local law enforcement or public safety official having independent authority for the test'' in paragraphs (g)(1) and (2). The additions to this phrase clarify that the officials that conduct post-accident testing to satisfy the requirements of these paragraphs are only law enforcement or public safety officials. This change is consistent with the original intent of this phrase when part 382 was added by FHWA. The notice of proposed rulemaking explained that the intent of paragraphs (g)(1) and (2), originally paragraph (f), was to ''allow motor carriers to accept tests done by law enforcement officials'' (57 FR 59516, 59522, Dec. 15, 1992). The final rule also stated that this provision applied to tests by ''on-site police or public safety officials'' (59 FR 7484, 7497, Feb. 15, 1994). Similar terms were used in guidance issued on section 382.303 (62 FR 16370, 16385, Apr. 4, 1997). Accordingly, FMCSA updates paragraphs (g)(1) and (2) to clarify that the officials referenced are law enforcement and public safety officials as originally intended when part 382 was added to the CFR.

D. Part 383—Commercial Driver's License Standards; Requirements and Penalties

Section 383.3 Applicability

FMCSA revises paragraph (f)(3)(ii) as directed by statute. Section 23019 of IIJA directs FMCSA to amend this section to provide that a restricted commercial driver's license issued to an employee in a farm-related service industry be limited to the applicable seasonal periods defined by the issuing State, with the condition that the total number of days in any calendar year during which the restricted CDL is valid does not exceed 210. (See IIJA section 23019). Accordingly, FMCSA revises the first sentence of paragraph (f)(3)(ii) to read, ''Restricted CDLs shall have the same renewal cycle as unrestricted CDLs but shall be limited to the seasonal period or periods as defined by the State of licensure, provided that the total number of days in any calendar year for which the restricted CDL is valid does not exceed 210.'' The revisions conform the FMCSRs with the language instructed in section 23019 of IIJA.

Section 383.73 State procedures

FMCSA revises § 383.73(q) to clarify that, as used in paragraph (q), the term ''downgrade'' means, specifically, the State's removal of the commercial learner's permit (CLP) or CDL privilege from the driver's license, as set forth in paragraph (4) of the definition of *CDL downgrade* in § 383.5. This amendment conforms to FMCSA's intent as described in its final rule ''Controlled Substances and Alcohol Testing: State Driver's Licensing Agency Non-issuance/Downgrade of Commercial Driver's License'' (86 FR 55718, Oct. 7, 2021). This revision is made in response to a petition for reconsideration of the October 2021 final rule submitted to FMCSA by the Oregon Department of Transportation (ODOT) on November 1, 2021, requesting that FMCSA clarify the meaning of the term ''downgrade'' as used in § 383.73(q).

The October 2021 final rule established requirements for State Driver Licensing Agencies (SDLA) to access and use information from FMCSA's Drug and Alcohol Clearinghouse indicating that a CLP or CDL holder or applicant cannot lawfully operate a CMV because they violated the drug and alcohol use and testing prohibitions in 49 CFR part 382, subpart B. Section 383.73(q) requires that the State, upon receiving notification that the CLP or CDL holder is prohibited from operating a CMV, initiate established State procedures for downgrading the CLP or CDL. The downgrade must be completed and recorded on the Commercial Driver's License Information System (CDLIS) driver record within 60 days of the State's receipt of such notification.

The intent of the CLP/CDL downgrade requirement in § 383.73(q), *i.e.,* the removal of the CLP or CDL from the driver's license, was clearly explained in the preamble to the October 2021 final rule: ''. . .SDLAs must remove the CLP or CDL privilege from the driver's license of an individual subject to the CMV driving prohibition, which would result in a downgrade of the license until the driver complies with return-to-duty (RTD) requirements'' (86 FR 55718). However, as ODOT pointed out, confusion may arise because the current definition of the term *CDL downgrade* in § 383.5 contains four alternative definitions. This revision clarifies that, as used in § 383.73(q), the term ''downgrade'' refers specifically to the fourth alternative definition, the removal of the CLP or CDL privilege from the driver's license.

E. Part 385—Safety Fitness Procedures

Sections 385.3 Definitions and Acronyms

FMCSA amends subparagraph (3) under the definition of *reviews* by adding a comma after the word ''policies.''

Appendix B to Part 385—Explanation of Safety Rating Process

FMCSA revises section VII of appendix B to part 385 by replacing the citation for § 382.305 with a citation to § 382.305(a). Currently, § 382.305 is listed in appendix B to part 385 as the citation for failing to implement a random controlled substances and/or an alcohol testing program. However, § 382.305 is the broad citation that encompasses all random testing violations, while the more specific citation should be § 382.305(a) for no random program. When the regulation was amended to add subsection (a), appendix B to part 385 was never amended. FMCSA now makes this conforming change.

F. Part 391—Qualifications of Drivers and Longer Combination Vehicle (LCV) Driver Instructors

Sections 391.23 Investigation and Inquiries

FMCSA removes the paragraph headings for paragraphs (c)(4), (g)(5), (m)(2), (m)(2)(i)(C), and (m)(3) to ensure consistency throughout § 391.23. Additionally, FMCSA deletes paragraph (e)(4)(i) and redesignates paragraphs (e)(4)(i)(A) and (B) as (e)(4)(i) and (ii), respectively. Prior to this change paragraph (e)(4) had a subparagraph (i), but no subparagraph (ii) which is not consistent with standard practice for paragraph levels in the CFR. FMCSA also adds the introductory text from paragraph (m)(2)(i) to the introductory text in paragraph (m)(2) and deletes paragraph (m)(2)(i) to remove a

paragraph (i) that was not accompanied by a paragraph (ii). Accordingly, FMCSA redesignates paragraphs (m)(2)(i)(A), (B), (B)(1), (2), and (C) as paragraphs (m)(2)(i), (ii), (ii)(A), (B), and (iii), respectively.

Section 391.25 Annual Inquiry and Review of Driving Record

FMCSA deletes the paragraph heading from paragraph (c) for consistency with the rest of § 391.25.

G. Part 395—Hours of Service of Drivers

Section 395.1 Scope of Rules in This Part

FMCSA revises paragraph (k) to reflect updated statutory authority for this part. Section 23018 of IIJA amended section 229(a)(1) of MCSIA (49 U.S.C. 31136 note) by adding a new exemption from the FMCSRs in part 395 regarding hours of service of drivers during planting and harvesting periods. The new exemption in section 229(a)(1)(D) of MCSIA applies to ''drivers transporting livestock (as defined in section 602 of the Emergency Livestock Feed Assistance Act of 1988 (7 U.S.C. 1471) including insects) within a 150 air-mile radius from the final destination of the livestock.'' The list of exemptions under section 229(a)(1) of MCSIA is currently codified in the FMCSRs at § 395.1(k). FMCSA is adding a new paragraph (4) to § 395.1(k) that mirrors the language from the amended section 229(a)(1)(D) of MCSIA so that the FMCSRs correctly reflect the exemptions from part 395 that are listed in FMCSA's statutory authority.

Section 395.8 Driver's Record of Duty Status

FMCSA revises a paragraph designation in § 395.8(a)(1)(iii)(A)(3) by italicizing the (3) in accordance with appropriate formatting of fifth level paragraphs in the CFR.[3]

H. Part 396—Inspection, Repair, and Maintenance

Appendix A to Part 396—Minimum Periodic Inspection Standards

FMCSA revises appendix A by emboldening and italicizing the titles for sections 1.l. (Antilock Brake System), 1.m. (Automatic Brake Adjusters), 14 (Motorcoach Seats), and 15 (Rear Impact Guard) for consistency with the rest of the titles in the appendix.

[3] See table 3–6 of the Document Drafting Handbook, National Archives and Records Administration (Jan. 7, 2022), available at *https://www.archives.gov/federal-register/write/handbook?msclkid=b4c92a20cf9d11ec998402835df7c864.*

FMCSA also updates the paragraphs in section 15 that were added in the November 9, 2021 final rule titled ''Parts and Accessories Necessary for Safe Operation; Rear Impact Guards and Rear Impact Protection'' (86 FR 62105). In the amendatory instructions for that final rule, FMCSA inadvertently designated certain paragraphs under section 15 as 1., 2., 3., etc. instead of (1), (2), (3), etc. This resulted in those paragraphs appearing in the CFR as first level paragraphs instead of third level paragraphs as intended. FMCSA redesignates these paragraphs to remedy this inadvertent error.

I. Part 397—Transportation of Hazardous Materials; Driving and Parking Rules

Section 397.71 Federal Standards

FMCSA revises footnote 1 by replacing ''(MC–EC)'' with ''(MC–SE).'' This change aligns regulatory text with updates to the internal organization of FMCSA and ensures that the correct office within the Agency is listed.

Section 397.73 Public Information and Reporting Requirements

FMCSA revises paragraph (b)(1)(ii) by replacing ''(MC–EC)'' with ''(MC–SE).'' This change aligns regulatory text with updates to the internal organization of FMCSA and ensures that information submitted under this section is directed to the correct office within the Agency.

Section 397.103 Requirements for State Routing Designations

FMCSA revises paragraph (c)(1)(ii) by replacing ''(MC–EC)'' with ''(MC–SE).'' This change aligns regulatory text with updates to the internal organization of FMCSA and ensures that written notices submitted under this section are directed to the correct office within the Agency.

III. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

This final rule is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and this final rule does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866. Accordingly, OMB has not reviewed it under that Order. In addition, this rule is not significant within the meaning of DOT regulations (49 CFR 5.13(a)). The amendments made in this final rule primarily correct inadvertent errors and omissions, remove or update obsolete references, and make minor language changes to improve clarity and consistency. Some changes are statutorily mandated or relate to previous changes that were statutorily mandated. In accommodating those changes, the Agency is performing nondiscretionary, ministerial acts. Other changes merely align regulatory requirements with the underlying statutory authority. None of the changes in this final rule imposes material new requirements or increases compliance obligations; therefore, this final rule imposes no new costs, and a full regulatory evaluation is unnecessary.

B. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801–808), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

C. Regulatory Flexibility Act (Small Entities)

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612), FMCSA is not required to complete a regulatory flexibility analysis because, as discussed earlier in the Legal Basis for the Rulemaking section, this action is not subject to notice and public comment under section 553(b) of the APA.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996), FMCSA wants to assist small entities in understanding this final rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please consult the person listed under the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you

wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $170 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2020 levels) or more in any 1 year. This final rule will not result in such an expenditure.

F. Paperwork Reduction Act (Collection of Information)

This final rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

G. E.O. 13132 (Federalism)

A rule has implications for federalism under section 1(a) of E.O. 13132 if it has ''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.'' FMCSA has determined that this rule will not have substantial direct costs on or for States, nor will it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005 (Pub. L. 108–447, 118 Stat. 2809, 3268, Dec. 8, 2004 (5 U.S.C. 552a note)), requires the Agency to conduct a privacy impact assessment of a regulation that will affect the privacy of individuals. Because this rule does not require the collection of personally identifiable information, the Agency is not required to conduct a privacy impact assessment.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002 (Pub. L. 107–347, sec. 208, 116 Stat. 2899, 2921, Dec. 17, 2002), requires Federal agencies to conduct a privacy impact assessment for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology will collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a privacy impact assessment.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

J. National Environmental Policy Act of 1969

FMCSA analyzed this rule pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, Mar. 1, 2004), Appendix 2, paragraphs 6.b, 6.c, and 6.t. These Categorical Exclusions address minor amendments and corrections to existing regulations (*e.g.,* concerning internal agency functions, organization, or personnel administration, etc.), and ensuring that States comply with the provisions of the Commercial Motor Vehicle Safety Act of 1986 by having the appropriate laws and policies, etc., concerning the qualification of licensing and persons who apply for or are issued a CDL. Therefore, preparation of an environmental assessment or environmental impact statement is not necessary.

List of Subjects

49 CFR Part 350

Grant programs-transportation, Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements, State and local governments.

49 CFR Part 360

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

49 CFR Part 380

Administrative practice and procedure, Highway safety, Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 382

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 385

Administrative practice and procedure, Highway safety, Mexico, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation.

49 CFR Part 395

Highway safety, Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 396

Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 397

Administrative practice and procedure, Hazardous materials transportation, Highway safety, Intergovernmental relations, Motor carriers, Parking, Radioactive materials, Reporting and recordkeeping requirements, Rubber and rubber products.

In consideration of the foregoing, FMCSA amends 49 CFR chapter III as set forth below:

PART 350—MOTOR CARRIER SAFETY ASSISTANCE PROGRAM (MCSAP) AND HIGH PRIORITY PROGRAM

■ 1. The authority citation for part 350 continues to read as follows:

Authority: 49 U.S.C. 504, 13902, 31101, 31102, 31104, 31106, 31108, 31136, 31141,

31161, 31310, 31311, 31502; secs. 5106 and 5107, Pub. L. 114–94, 129 Stat. 1312, 1530; and 49 CFR 1.87.

§ 350.221 [Amended]

■ 2. Amend § 350.221 by removing the words ''next full Federal fiscal year'' and adding in their place ''next 2 full Federal fiscal years''.

§ 350.227 [Amended]

■ 3. In § 350.227, amend paragraph (c)(2)(ii) by removing the words ''2004 and 2005'' and adding the words ''2014 and 2015'' in their place.

■ 4. Amend § 350.403 by:
■ a. Revising paragraph (h);
■ b. In paragraph (i) removing the word ''or'';
■ c. Redesignating paragraph (j) as paragraph (k); and
■ d. Adding a new paragraph (j).

The revision and addition read as follows:

§ 350.403 What are the High Priority Program objectives?

* * * * *

(h) Advance the technological capability and promote the Innovative Technology Deployment of intelligent transportation system applications for CMV operations by States, including technology to detect, and enforce actions taken as a result of, criminal activity (including human trafficking) in a CMV or by any occupant of a CMV, including the operator;

* * * * *

(j) Support the recognition, prevention, and reporting of human trafficking in a CMV or by any occupant of a CMV, including the operator, and enforce laws relating to human trafficking; or

* * * * *

§ 350.405 [Amended]

■ 5. In § 350.405, amend paragraph (a) by removing the words '', (i), and (j)'' and adding the words ''and (i) through (k)'' in their place.

§ 350.411 [Amended]

■ 6. In § 350.411, amend paragraph (a) by removing the phrase '', (i), and (j)'' and adding the phrase ''and (i) through (k)'' in its place.

PART 360—FEES FOR MOTOR CARRIER REGISTRATION AND INSURANCE

■ 7. The authority citation for part 360 continues to read as follows:

Authority: 31 U.S.C. 9701; 49 U.S.C. 13908; and 49 CFR 1.87.

■ 8. Amend § 360.3 as follows:
■ a. Lift the suspension of the section;
■ b. Revise paragraph (e)(3)(iii); and
■ c. Suspend the section indefinitely.

The revision reads as follows:

§ 360.3 Filing fees.

* * * * *

(e) * * *

(3) * * *

(iii) *FMCSA action.* FMCSA will notify the applicant of the decision to grant or deny the request for waiver or reduction.

■ 9. Amend § 360.3T by revising paragraph (e)(2)(iii) to read as follows:

§ 360.3T Filing fees.

* * * * *

(e) * * *

(2) * * *

(iii) *Federal Motor Carrier Safety Administration action.* The Federal Motor Carrier Safety Administration will notify the applicant of the decision to grant or deny the request for waiver or reduction.

* * * * *

PART 380—SPECIAL TRAINING REQUIREMENTS

■ 10. The authority citation for part 360 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31305, 31307, 31308, 31502; sec. 4007(a) and (b), Pub. L. 102–240, 105 Stat. 1914, 2151–2152; sec. 32304, Pub. L. 112–141, 126 Stat. 405, 791; and 49 CFR 1.87.

§ 380.703 [Amended]

■ 11. In § 380.703(a)(7) and (b), remove the words ''website'' and add, in their place, the word ''website''.

§ 380.717 [Amended]

■ 12. In the introductory text to § 380.717, remove the words ''website'' and add, in their place, the word ''website''.

■ 13.Amend § 380.723 by revising paragraphs (a) and (b) to read as follows:

§ 380.723 Removal from training provider registry: procedure.

(a) *Voluntary removal.* To be voluntarily removed from the Training Provider Registry (TPR), a provider must submit written notice to FMCSA, ATTN: Training Provider Registry Removal, 1200 New Jersey Avenue SE, Washington, DC 20590 or through the TPR website. Upon receiving the written notice, FMCSA will remove the training provider from the TPR. On and after the date of issuance of a notice of proposed removal from the TPR issued in accordance with paragraph (b) of this section, such a voluntary removal notice will not be effective.

(b) *Involuntary removal; Notice of proposed removal.* Except as provided by paragraphs (a) and (e) of this section, FMCSA initiates the process for involuntary removal of a provider from the TPR by issuing a written notice to the provider, stating the reasons for the proposed removal and setting forth any corrective actions necessary for the provider to remain listed on the TPR. If a notice of proposed removal is issued, the provider must notify current driver-trainees and driver-trainees scheduled for future training of the proposed removal. If a notice of proposed removal is issued to a training provider listed on the TPR website, FMCSA will note on the TPR website that such notice has been issued. FMCSA will remove the notation if the notice is withdrawn.

* * * * *

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

■ 14. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31301 *et seq.,* 31502; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

§ 382.119 [Amended]

■ 15. Amend § 382.119(e) by removing the words ''Office of Enforcement and Compliance (MC–EC)'' and adding the words ''Office of Safety Programs (MC–SS)'' in their place.

■ 16. Amend § 382.303 by revising paragraph (g) to read as follows:

§ 382.303 Post-accident testing.

* * * * *

(g)(1) The results of a breath or blood test for the use of alcohol, conducted by Federal, State, or local law enforcement or public safety officials having independent authority for the test, shall be considered to meet the requirements of this section, provided such tests conform to the applicable Federal, State or local alcohol testing requirements, and that the results of the tests are obtained by the employer.

(2) The results of a urine test for the use of controlled substances, conducted by Federal, State, or local law enforcement or public safety officials having independent authority for the test, shall be considered to meet the requirements of this section, provided such tests conform to the applicable Federal, State or local controlled substances testing requirements, and that the results of the tests are obtained by the employer.

* * * * *

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 17. The authority citation for part 383 is revised to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 *et seq.,* and 31502; secs. 214 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56, 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 23019 of Pub. L. 117–58, 135 Stat. 429, 777; and 49 CFR 1.87.

■ 18. Amend § 383.3 by revising paragraph (f)(3)(ii) to read as follows:

§ 383.3 Applicability.

* * * * *

(f) * * *

(3) * * *

(ii) Restricted CDLs shall have the same renewal cycle as unrestricted CDLs but shall be limited to the seasonal period or periods as defined by the State of licensure, provided that the total number of days in any calendar year for which the restricted CDL is valid does not exceed 210. If a State elects to provide for more than one seasonal period, the restricted CDL is valid for commercial motor vehicle operation only during the currently approved season, and must be revalidated for each successive season. Only one seasonal period of validity may appear on the license document at a time. The good driving record must be confirmed prior to any renewal or revalidation.

* * * * *

■ 19. Amend § 383.73 by revising paragraph (q) introductory text to read as follows:

§ 383.73 State procedures.

* * * * *

(q) *Drug and Alcohol Clearinghouse.* Beginning November 18, 2024, the State must, upon receiving notification that pursuant to § 382.501(a) of this chapter the CLP or CDL holder is prohibited from operating a commercial motor vehicle, initiate established State procedures for downgrading the CLP or CDL. The downgrade must be completed and recorded on the CDLIS driver record within 60 days of the State's receipt of such notification. As used in this paragraph, the term ''downgrade'' means the State's removal of the CLP or CDL privilege from the driver's license, as set forth in paragraph (4) the definition of *CDL downgrade* in § 383.5.

* * * * *

PART 385—SAFETY FITNESS PROCEDURES

■ 20. The authority citation for part 385 continues to read as follows:

Authority: 49 U.S.C. 113, 504, 521(b), 5105(d), 5109, 5113, 13901–13905, 13908, 31135, 31136, 31144, 31148, 31151, 31502; sec. 113(a), Pub. L. 103–311, 108 Stat. 1673, 1676; sec. 408, Pub. L. 104–88, 109 Stat. 803, 958; sec. 350, Pub. L. 107–87, 115 Stat. 833, 864; sec. 5205, Pub. L. 114–94, 129 Stat. 1312, 1537; and 49 CFR 1.87.

§ 385.3 [Amended]

■ 21. In § 385.3 amend the definition of ''Reviews'' by adding a comma after the word ''policies'' in paragraph (3).

Appendix B to Part 385 [Amended]

■ 22. Amend section VII of appendix B to part 385 by removing the reference ''§ 382.305'' and adding, in its place, the reference ''§ 382.305(a)''.

PART 391—QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION VEHICLE (LCV) DRIVER INSTRUCTORS

■ 23. The authority citation for part 391 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31133, 31136, 31149, 31502; sec. 4007(b), Pub. L. 102–240, 105 Stat. 1914, 2152; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215, Pub. L. 106–159, 113 Stat. 1748, 1767; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; secs. 5403 and 5524, Pub. L. 114–94, 129 Stat. 1312, 1548, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; and 49 CFR 1.87.

■ 24. Amend § 391.23 by revising paragraphs (c)(4), (e)(4), (g)(5), (m)(2), and (m)(3) introductory text to read as follows:

§ 391.23 Investigation and inquiries.

* * * * *

(c) * * *

(4) For drivers with no previous employment experience working for a DOT-regulated employer during the preceding three years, documentation that no investigation was possible must be placed in the driver investigation history file, after October 29, 2004, within the required 30 days of the date the driver's employment begins.

* * * * *

(e) * * *

(4) As of January 6, 2023, employers subject to § 382.701(a) of this chapter must use the Drug and Alcohol Clearinghouse to comply with the requirements of this section with respect to FMCSA-regulated employers.

(i) If an applicant who is subject to follow-up testing has not successfully completed all follow-up tests, the employer must request the applicant's follow-up testing plan directly from the previous employer in accordance with § 40.25(b)(5) of this title.

(ii) If an applicant was subject to an alcohol and controlled substance testing program under the requirements of a DOT mode other than FMCSA, the employer must request alcohol and controlled substances information required under this section directly from those employers regulated by a DOT mode other than FMCSA.

* * * * *

(g) * * *

(5) Until May 1, 2006, carriers need only provide information for accidents that occurred after April 29, 2003.

(m) * * *

(2) For drivers required to have a commercial driver's license under part 383 of this chapter, beginning January 30, 2015, using the CDLIS motor vehicle record obtained from the current licensing State, the motor carrier must verify and document in the driver qualification file the following information before allowing the driver to operate a CMV:

(i) The type of operation the driver self-certified that he or she will perform in accordance with § 383.71(b)(1) of this chapter.

(ii)(A) Beginning on May 21, 2014, and through June 22, 2025, that the driver was certified by a medical examiner listed on the National Registry of Certified Medical Examiners as of the date of medical examiner's certificate issuance.

(B) If the driver has certified under paragraph (m)(2)(i)(A) of this section that he or she expects to operate in interstate commerce, that the driver has a valid medical examiner's certificate and any required medical variances.

(iii) Beginning on January 30, 2015, and through June 22, 2025, if the driver provided the motor carrier with a copy of the current medical examiner's certificate that was submitted to the State in accordance with § 383.73(b)(5) of this chapter, the motor carrier may use a copy of that medical examiner's certificate as proof of the driver's medical certification for up to 15 days after the date it was issued.

(3) For drivers required to have a commercial learner's permit under part 383 of this chapter:

* * * * *

§ 391.25 [Amended]

■ 25. Amend § 391.25 by removing the paragraph (c) heading.

PART 395—HOURS OF SERVICE OF DRIVERS

■ 26. The authority citation for part 395 continues to read as follows:

Authority: 49 U.S.C. 504, 21104(e), 31133, 31136, 31137, 31502; sec. 113, Pub. L. 103–311, 108 Stat. 1673, 1676; sec. 229, Pub. L. 106–159 (as added and transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743, 1744), 113 Stat. 1748, 1773; sec. 4133, Pub. L. 109–59, 119 Stat. 1144, 1744; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; sec. 5206(b), Pub. L. 114–94, 129 Stat. 1312, 1537; and 49 CFR 1.87.

■ 27. In § 395.1 amend paragraph (k) by:
■ a. In paragraph (k)(2) removing the word ''or'';
■ b. In paragraph (k)(3) removing ''.'' and adding ''; or'' in its place; and
■ c. Adding paragraph (k)(4).
The addition reads as follows:

§ 395.1 Scope of rules in this part.

* * * * *

(k) * * *

(4) Livestock (as defined in section 602 of the Emergency Livestock Feed Assistance Act of 1988 (7 U.S.C. 1471) including insects)) within a 150 air-mile radius from the final destination of the livestock.

PART 396—INSPECTION, REPAIR, AND MAINTENANCE

■ 28. The authority citation for part 396 continues to read as follows:

Authority: 49 U.S.C. 504, 31133, 31136, 31151, 31502; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524, Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 29. Amend appendix A to part 396 by:
■ a. In section 1 revising the section heading and the headings of paragraphs 1.l and m;
■ b. In section 14 revising the section heading; and
■ c. Revising section 15.
The revisions read as follows:

Appendix A to Part 396—Minimum Periodic Inspection Standards

* * * * *

1. *Brake System.*

* * * * *

l. *Antilock Brake System*[1 2 3]

* * * * *

m. *Automatic Brake Adjusters*

* * * * *

14. *Motorcoach Seats.*

* * * * *

15. *Rear Impact Guard.*

a. Trailers and semitrailers with a GVWR of 4,536 kg (10,001 lbs.) or more, manufactured on or after January 26, 1998 (see exceptions in § 393.86(a)(1) of this subchapter).

(1) Missing guard.

(2) Guard is not securely attached to trailer, including broken or missing fasteners, any welds or parent metal cracked, or other damage that compromises secure attachment of the guard.

(3) Guard horizontal member does not extend to within 100 mm (4 inches) of each, or extends beyond either, side extremity of the vehicle.

(4) Guard horizontal member is more than 560 mm (22 inches) above the ground.

(5) Guard horizontal member is more than 305 mm (12 inches) forward of the rear extremity of the vehicle.

(6) Guard horizontal member does not have a cross sectional vertical height of at least 100 mm (4 inches) across its entire width.

b. Commercial motor vehicles manufactured after December 31, 1952 (except trailers and semitrailers manufactured on or after January 26, 1998) (see exceptions in § 393.86(b)(1) and 393.86(b)(3) of this subchapter).

(1) Missing guard.

(2) Guard is not securely attached to trailer by bolts, welding, or other comparable means.

(3) Guard horizontal member is more than 762 mm (30 inches) above the ground.

(4) Guard horizontal member does not extend to within 457 mm (18 inches) of each side extremity of the vehicle.

(5) Guard horizontal member is more than 610 mm (24 inches) forward of the rear extremity of the vehicle.

PART 397—TRANSPORTATION OF HAZARDOUS MATERIALS; DRIVING AND PARKING RULES

■ 30. The authority citation for part 397 continues to read as follows:

Authority: 49 U.S.C. 322; 49 CFR 1.87. Subpart A also issued under 49 U.S.C. 5103, 31136, 31502, and 49 CFR 1.97. Subparts C, D, and E also issued under 49 U.S.C. 5112, 5125.

§ 397.71 [Amended]

■ 31. In § 397.71 amend footnote 1 by removing the words ''(MC–EC)'' and adding the words ''(MC–SE)'' in their place.

§ 397.73 [Amended]

■ 32. Amend § 397.73(b)(1)(ii) by removing the words ''(MC–EC)'' and adding the words ''(MC–SE)'' in their place.

§ 397.103 [Amended]

■ 33. Amend § 397.103(c)(1)(ii) by removing the words ''(MC–EC)'' and adding the words ''(MC–SE)'' in their place.

Issued under authority delegated in 49 CFR 1.87.

Robin Hutcheson,

Deputy Administrator.

[FR Doc. 2022–20644 Filed 9–28–22; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register
Vol. 87, No. 188
Thursday, September 29, 2022

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.

DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Alimentarius Commission

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S. Codex Office is sponsoring a virtual public meeting on October 26, 2022. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 45th Session of the Codex Alimentarius Commission (CAC), which will take place from November 21–25, 2022, with the report adoption on December 12–13, 2022. The U.S. Manager for Codex Alimentarius and the Acting Deputy Under Secretary for Trade and Foreign Agricultural Affairs recognize the importance of providing interested parties the opportunity to obtain background information on the 45th Session of the CAC and to address items on the agenda.

DATES: The public meeting is scheduled for October 26, 2022, from 1:00 p.m.–4:00 p.m. EST.

ADDRESSES: The public meeting will take place via video teleconference only. Documents related to the 45th Session of the CAC will be accessible via the internet at the following address: *https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=45.* Ms. Mary Frances Lowe, U.S. Delegate to the 45th Session of the CAC, invites interested U.S. parties to submit their comments electronically to the following email address: *uscodex@usda.gov.*

Registration: Attendees may register to attend the public meeting here: *https://www.zoomgov.com/meeting/register/vJItdO-srDMrGJxRIsmy7r4RU08yTLgsaEE.* After registering, you will receive a confirmation email containing information about joining the meeting.

For further information about the 45th Session of the CAC or the public meeting, please contact the U.S. Codex Office, 1400 Independence Avenue SW, Room 4861, South Agriculture Building, Washington, DC 20250. Phone (202) 205–7760. Email: *uscodex@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission was established in 1963 by two United Nations organizations: the Food and Agriculture Organization and the World Health Organization. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade; promotes coordination of all food standards work undertaken by international governmental and nongovernmental organizations; determines priorities, initiates, and guides the preparation of draft standards; finalizes the standards elaborated and publishes them in a Codex Alimentarius (food code) either as regional or worldwide standards, wherever this is practicable; and amends published standards, as appropriate, in the light of new developments.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 45th Session of the CAC will be discussed during the public meeting:

- Report by the Chairperson on the 82nd and 83rd Sessions of the Executive Committee (including matters referred)
- Amendments to the Procedural Manual
- Work of Codex Committees (adoption, new work, revocation, discontinuation and editorial amendments to Codex texts proposed by the following committees):
  - Codex Committee on Fats and Oils
  - Codex Committee on Nutrition and Foods for Special Dietary Uses
  - Codex Committee on Food Hygiene
  - Codex Committee on Fresh Fruits and Vegetables
  - Codex Committee on Contaminants in Foods
  - Codex Committee on Pesticide Residues
  - Codex Committee on Spices and Culinary Herbs
  - Codex Committee on Residues of Veterinary Drugs in Foods
  - FAO/WHO Regional Coordinating Committees
- Editorial amendments to Codex texts proposed by the Codex Secretariat
- Other matters related to Codex Subsidiary Bodies
- Codex Strategic Plan 2020–2025—Implementation report 2020–2021
- Codex Budgetary and Financial Matters
- Matters arising from FAO and WHO
- Appointment of Coordinators
- Election of Chairperson and Vice-Chairpersons
- Designation of Countries responsible for appointing the Chairpersons of Codex Subsidiary Bodies
- 60th Anniversary of the Codex Alimentarius Commission: 1963–2023

Relevant documents are or will be available at *https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=45.*

Public Meeting

At the October 26, 2022, public meeting, draft U.S. positions on the anticipated agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 45th Session of the CAC (see **ADDRESSES**). Written comments should state that they relate to activities of the 45th Session of the CAC.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the USDA web page located at: *https://www.usda.gov/codex,* a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscription themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race,

color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, 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.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *https://www.usda.gov/sites/default/files/documents/Complain_combined_6_8_12_508.pdf,* or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email.

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410. Fax: (202) 690–7442. Email: *program.intake@usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on September 25, 2022.

Mary Frances Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2022–21091 Filed 9–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the New Mexico Advisory Committee; Correction

AGENCY: Commission on Civil Rights.

ACTION: Notice; correction.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** on Tuesday, August 23, 2022, concerning a meeting of the New Mexico Advisory Committee. The meeting link has since been updated.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, *bpeery@usccr.gov,* (312) 353–8311.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** on Tuesday, August 23, 2022, in FR Document Number 2022–18090, on page 51650, second column, correct the meeting link to read: *https://www.zoomgov.com/meeting/register/vJIscO-grzkoEiGG6UBK47iBlZk2oWeQX3w.*

Dated: September 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21183 Filed 9–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the American Samoa Advisory Committee; Correction

AGENCY: Commission on Civil Rights.

ACTION: Notice; correction.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** on Friday, July 8, 2022, concerning a meeting of the American Samoa Advisory Committee. The meeting link has since been updated.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, *bpeery@usccr.gov,* (312) 353–8311.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** on Friday, July 8, 2022, in FR Document Number 2022–14527, on page 40783, first and second columns, correct the meeting link to read: *https://www.zoomgov.com/meeting/register/vJIsduqhqTwoHGxw-mEIXfL0LR9nNmGxylI.*

Dated: September 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21174 Filed 9–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the South Carolina Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the South Carolina Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a business meeting on Friday, October 14, 2022, at 12:00 p.m. (ET). The purpose of the meeting is to review, edit, and vote on the committee's draft report on civil asset forfeiture.

DATES: October 14, 2022, Friday, at 12:00 p.m. (ET).

ADDRESSES:

Meeting Link (Audio/Visual): https://tinyurl.com/5zw3edej; password, if needed: USCCR-SC.

Telephone (Audio Only): Dial 1–551–285–1373 USA Toll Free; Meeting ID: 160 855 9617#.

FOR FURTHER INFORMATION CONTACT: Barbara de La Viez, DFO, at *bdelaviez@usccr.gov* or (202) 376–8473.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *ero@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, South Carolina Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above email or street address.

Agenda

I. Roll Call

II. Discussion: Review, Edit, and Vote on Civil Asset Forfeiture Report

III. Other Business

IV. Public Comment

V. Next Steps

VI. Adjournment

Dated: September 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21168 Filed 9–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the New Mexico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the New Mexico Advisory Committee (Committee) will hold a series of virtual meetings via ZoomGov on the following dates and times for the purpose of discussing planning and debriefing panels on education adequacy for Native American students.

DATES: These meetings will take place on:

- Tuesday, November 1, 2022, from 12:00 p.m.–1:00 p.m. MT.
- Tuesday, November 15, 2022, from 12:00 p.m.–1:00 p.m. MT.

ADDRESSES:

Public Registration Link for Both Meetings:

- Tuesday, November 1st and Tuesday, November 15th: *https://www.zoomgov.com/meeting/register/vJItfuusrD4sHB8-CS_XiU5s_2WqzppWGAE*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO), at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 300 N. Los Angeles St., Suite 2010, Los Angeles, CA 90012 or emailed to Brooke Peery at *bpeery@usccr.gov*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlGAAQ.*

Please click on the ''Meeting Details'' and ''Documents'' links. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Approval of Minutes
III. Committee Discussion
IV. Public Comment
V. Adjournment

Dated: September 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21178 Filed 9–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the New Mexico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the New Mexico Advisory Committee (Committee) will hold a series of virtual meetings via ZoomGov on the following dates and times for the purpose of discussing planning and debriefing panels on education adequacy for Native American students.

DATES: These meetings will take place on:

- Tuesday, November 1, 2022, from 12:00 p.m.–1:00 p.m. MT.
- Tuesday, November 15, 2022, from 12:00 p.m.–1:00 p.m. MT.

ADDRESSES:

Public Registration Link for Both Meetings:

- Tuesday, November 1st and Tuesday, November 15th: *https://www.zoomgov.com/meeting/register/vJItfuusrD4sHB8-CS_XiU5s_2WqzppWGAE.*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO), at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 300 N. Los Angeles St., Suite 2010, Los Angeles, CA 90012 or emailed to Brooke Peery at *bpeery@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlGAAQ.*

Please click on the ''Meeting Details'' and ''Documents'' links. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit

office at the above email or street address.

Agenda

I. Welcome and Roll Call

II. Approval of Minutes

III. Committee Discussion

IV. Public Comment

V. Adjournment

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21177 Filed 9–28–22; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–137–2022]

Approval of Expansion of Subzone 61Z; Oldach Associates, LLC; Cataño, Puerto Rico

On August 8, 2022, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Department of Economic Development and Commerce, grantee of FTZ 61, requesting an expansion of Subzone 61Z subject to the existing activation limit of FTZ 61, on behalf of Oldach Associates, LLC, in Cataño, Puerto Rico.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (87 FR 49580, August 11, 2022). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to expand Subzone 61Z was approved on September 26, 2022, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 61's 1,821.07-acre activation limit.

Dated: September 26, 2022.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2022–21115 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–856]

Oil Country Tubular Goods From Mexico: Final Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of oil country tubular goods (OCTG) from Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV) during the period of investigation October 1, 2020, through September 30, 2021.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Emily Bradshaw or Yang Jin Chun, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3896 or (202) 482–5760, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2022, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of OCTG from Mexico, in which it also postponed the final determination until September 23, 2022.[1] We invited interested parties to comment on the *Preliminary Determination.* A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The products covered by this investigation are OCTG from Mexico. For a complete description of the scope of this investigation, *see* appendix I.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as appendix II. 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.*

Verification

Commerce was unable to conduct on-site verifications of the information relied upon in making its final determination in this investigation for reasons beyond its control. However, we conducted virtual verifications in lieu of on-site verifications to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, Commerce conducted virtual verifications of the home market sales, U.S. sales, cost of production, and further manufacturing responses submitted by Tubos de Acero de Mexico, S.A. (TAMSA).

Changes Since the Preliminary Determination

Based on our analysis of the comments received and additional information obtained since the *Preliminary Determination,* we made certain changes to the margin calculation for this final determination. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for individually investigated exporters and producers, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act, *i.e.,* facts otherwise available.

In this investigation, Commerce calculated an individual estimated weighted-average dumping margin for the sole mandatory respondent, TAMSA, that is not zero, *de minimis,* or

[1] *See Oil Country Tubular Goods from Mexico: Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 87 FR 28808 (May 11, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Oil Country Tubular Goods from Mexico: Issues and Decision Memorandum for the Final Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

based entirely on facts otherwise available. Consequently, Commerce assigned the estimated weighted-average dumping margin calculated for TAMSA to all other producers and exporters of the merchandise under consideration, pursuant to section 735(c)(5)(A) of the Act.

Final Affirmative Determination of Critical Circumstances

In accordance with section 735(a)(3) of the Act and 19 CFR 351.206, Commerce continues to find that critical circumstances exist for all companies in Mexico. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Issues and Decision Memorandum.[3]

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist for the period October 1, 2020, through September 30, 2021:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Tubos de Acero de Mexico, S.A	44.93
All Others	44.93

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 11, 2022, the date of publication of the *Preliminary Determination* in the **Federal Register**. Further, in accordance with 735(c)(4) of the Act, Commerce will instruct CBP to continue to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after February 10, 2022, which is 90 days before the date of publication of the *Preliminary Determination* in the **Federal Register**. These suspension of liquidation instructions will remain in effect until further notice.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rate for the respondent listed in the table above is the company-specific estimated weighted-average dumping margin listed for the respondent in the table; (2) if the exporter is not the respondent listed in the table above, but the producer is, then the cash deposit rate is the company-specific estimated weighted-average dumping margin listed for the producer of the subject merchandise in the table above; and (3) the cash deposit rate for all other producers and exporters is the all-others estimated weighted-average dumping margin listed in the table above.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its final affirmative determination of sales at LTFV. Because the final determination in this investigation is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of OCTG no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the ''Continuation of Suspension of Liquidation'' section above.

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). 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 sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of this investigation also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the OCTG.

Excluded from the scope of this investigation are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160, 7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

[3] *See* Issues and Decision Memorandum at 3–4.

The merchandise subject to this investigation may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–21170 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–010, C–570–011]

Certain Crystalline Silicon Photovoltaic Products From the People's Republic of China: Notice of Initiation of Changed Circumstances Reviews, and Consideration of Revocation of the Antidumping and Countervailing Duty Orders, in Part

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

SUMMARY: Based on a request from Shenzhen Hello Tech Energy Co., Ltd. (Hello Tech), the U.S. Department of Commerce (Commerce) is initiating changed circumstances reviews (CCR) to consider the possible revocation, in part, of the antidumping duty (AD) and countervailing duty (CVD) orders on certain crystalline silicon photovoltaic products (solar products) from the People's Republic of China (China) with respect to certain off-grid small portable crystalline silicon photovoltaic (CSPV) panels as described below.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Daniel Alexander, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4313.

SUPPLEMENTARY INFORMATION:

Background

On February 18, 2015, Commerce published the AD and CVD orders on solar products from China.[1] On August 8, 2022, Hello Tech, a Chinese producer and exporter of subject merchandise, requested, through CCRs, revocation of the *Orders,* in part, with respect to CSPV panels, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(b).[2] Within Hello Tech's CCR request, Hello Tech included a letter from the American Alliance for Solar Manufacturing (the Alliance), a U.S. producer of the domestic like product and a petitioner in the underlying investigations, in which the Alliance stated that it did not oppose the partial revocation of the *Orders* proposed by Hello Tech.[3] No interested parties filed comments opposing the CCR request.

Scope of the *Orders*

The merchandise covered by these *Orders* is modules, laminates and/or panels consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including building integrated materials. For purposes of these *Orders,* subject merchandise includes modules, laminates and/or panels assembled in China consisting of crystalline silicon photovoltaic cells produced in a customs territory other than China.

Subject merchandise includes modules, laminates and/or panels assembled in China consisting of crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Excluded from the scope of the *Orders* are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS). Also excluded from the scope of these *Orders* are modules, laminates and/or panels assembled in China, consisting of crystalline silicon photovoltaic cells, not exceeding 10,000 mm2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cells. Where more than one module, laminate and/or panel is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all modules, laminates and/or panels that are integrated into the consumer good.

Further, also excluded from the scope of these *Orders* are any products covered by the existing antidumping and countervailing duty orders on crystalline silicon photovoltaic cells, whether or not assembled into modules, laminates and/or panels, from China.

Additionally, excluded from the scope of these *Orders* are solar panels that are: (1) less than 300,000 mm2 in surface area; (2) less than 27.1 watts in power; (3) coated across their entire surface with a polyurethane doming resin; and (4) joined to a battery charging and maintaining unit (which is an acrylonitrile butadiene styrene (ABS) box that incorporates a light emitting diode (LED)) by coated wires that include a connector to permit the incorporation of an extension cable. The battery charging and maintaining unit utilizes high-frequency triangular pulse waveforms designed to maintain and extend the life of batteries through the reduction of lead sulfate crystals. The above-described battery charging and maintaining unit is currently available under the registered trademark ''SolarPulse.''

Also excluded from the scope of these *Orders* are off-grid crystalline silicon photovoltaic panels without a glass cover with the following characteristics: (1) total power output of 500 watts or

[1] *See Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 Fr 8592 (February 18, 2015) (*Orders*).

[2] *See* Hello Tech's Letter, ''Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Hello Tech's Resubmitted Request for Changed Circumstances Reviews,'' dated August 8, 2022 (CCR Request).

[3] *Id.* at Exhibit 7.

less per panel; (2) maximum surface area of 8,000 cm2 per panel; (3) unit does not include a built-in inverter; (4) unit has visible parallel grid collector metallic wire lines every 2–40 millimeters across each solar panel (depending on model); (5) solar cells are encased in laminated frosted PET material without stitching; [4] (6) the panel is encased in polyester fabric with visible stitching which includes a Velcro-type storage pocket and unit closure, or encased within a Neoprene clamshell (depending on model); and (7) includes LED indicator.

Merchandise covered by these *Orders* is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 8501.61.0000, 8507.20.8030, 8507.20.8040, 8507.20.8060, 8507.20.8090, 8541.40.6015, 8541.40.6020, 8541.40.6030, 8541.40.6035 and 8501.31.8000. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of these *Orders* is dispositive.

Proposed Partial Revocation of the *Orders*

The products subject to the proposed revocation are off-grid portable small crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics:

(A) total power output of 200 watts or less per panel;

(B) a maximum surface area of 16,000 cm2 per panel;

(C) do not include a built-in inverter;

(D) must include an integrated handle or a handle attached to the package for ease of carry;

(E) must include one or more integrated kickstands for easy installation or angle adjustment; and

(F) must include a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8mm diameter male barrel connector.

Initiation of CCRs and Consideration of Revocation of the *Orders*, in Part

Pursuant to section 751(b) of the Act, when Commerce receives information concerning, or a request from an interested party [5] for a review of, a final affirmative determination that resulted in an AD or CVD order, which shows changed circumstances sufficient to warrant a review of an order, Commerce shall conduct a changed circumstances review of the order.[6] In accordance with 19 CFR 351.216(d), Commerce determines that the information submitted by Hello Tech, and the letter of no opposition to partial revocation of the *Orders* with respect to the products described by Hello Tech, constitute a sufficient basis to conduct CCRs of the *Orders*.[7]

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that Commerce may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. In addition, in the event that Commerce determines an expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits Commerce to combine the notices of initiation and preliminary results. In its administrative practice, Commerce has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[8]

One domestic producer, the Alliance, stated that it does not object to the partial revocation of the *Orders* proposed by Hello Tech. However, because the Alliance did not indicate whether it accounts for substantially all of the U.S. production of the domestic like product covered by the *Orders,* we are not combining this notice of initiation with a preliminary determination, pursuant to 19 CFR 351.221(c)(3)(ii). Rather, we will provide interested parties with an opportunity to address the issue of domestic industry support with respect to the partial revocation of the *Orders,* as explained below. After examining comments, if any, concerning domestic industry support, we will issue the preliminary results of these CCRs.

Public Comment

Interested parties are invited to provide comments and/or factual information regarding these CCRs, including comments on industry support and the proposed partial revocation language. Comments and factual information may be submitted to Commerce no later than 14 days after the date of publication of this notice. Rebuttal comments and rebuttal factual information may be filed with Commerce no later than seven days after the comments and/or factual information are filed.[9] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[10] An electronically-filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time on the due dates set forth in this notice. Note that Commerce has temporarily modified certain requirements for serving documents containing business proprietary information, until further notice.[11]

Preliminary and Final Results of the CCRs

Commerce intends to publish in the **Federal Register** a notice of the preliminary results of these AD and CVD CCRs in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice. Unless extended, Commerce will issue the final results of these CCRs in accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act and 19 CFR 351.221(b)(1).

Dated: September 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–21129 Filed 9–28–22; 8:45 am]

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[4] Although the polyester material has stitching on the perimeter of the unit, the cells are not stitched into the PET material.

[5] Hello Tech stated in its August CCR Request that it is an exporter of solar panels. As such, Hello Tech is an interested party pursuant to section 771(9)(A) of the Act and 19 CFR 351.102(b)(29)(i).

[6] *See* 19 CFR 351.216(d).

[7] *See* CCR Request at Exhibit 7.

[8] *See, e.g., Certain Cased Pencils from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent To Revoke Order in Part,* 77 FR 42276 (July 18, 2012), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination To Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

[9] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2).

[10] *See generally* 19 CFR 351.303.

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–833]

Oil Country Tubular Goods From the Russian Federation: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Affirmative Critical Circumstances Determination, in Part

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of oil country tubular goods (OCTG) from the Russian Federation (Russia) are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation (POI) October 1, 2020, through September 30, 2021.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: George McMahon or Mike Heaney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1167 or (202) 482–4475, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2022, Commerce published in the **Federal Register** the preliminary affirmative determination in the LTFV investigation of OCTG from Russia, in which it also postponed the final determination until September 23, 2022.[1] We invited interested parties to comment on the *Preliminary Determination.* A summary of the events that occurred since Commerce published the *Preliminary Determination* may be found in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is OCTG from Russia. For a complete description of the scope of this investigation, *see* appendix I.

Analysis of Comments Received

All the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as appendix II. 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.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation for reasons beyond its control. However, we conducted virtual verifications in lieu of an on-site verification to verify the information relied upon in making this final determination with respect to JSC Vyksa Steel Works (OMK/VSW), in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3] Specifically, Commerce conducted virtual verifications of OMK/VSW's information and data on home market sales, U.S. sales, and cost of production.

Changes Since the Preliminary Determination

Based on our analysis of the comments received, we have made certain changes to the margin calculations for OMK/VSW, and we applied a margin based on adverse facts available for Volzhsky Pipe Plant, Joint Stock Company (TMK/VTZ). For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act (*i.e.,* facts otherwise available).

Commerce calculated an individual estimated weighted-average dumping margin for OMK/VSW and assigned a rate based entirely on facts available to TMK/VTZ, the two respondents selected for individual examination in this investigation. Because the only individually calculated dumping margin that is not zero, *de minimis,* or based entirely on facts otherwise available, is the estimated weighted-average dumping margin calculated for OMK/VSW, we have assigned the margin calculated for OMK/VSW to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Final Affirmative Determination of Critical Circumstances, in Part

In accordance with section 735(a)(3) of the Act and 19 CFR 351.206(h), we find that critical circumstances exist for certain companies in Russia. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the ''Final Affirmative Determination of Critical Circumstances, in Part'' section of the Issues and Decision Memorandum.

Final Determination

The final estimated weighted-average dumping margins are as follows:

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[1] *See Oil Country Tubular Goods from the Russian Federation: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Critical Circumstances Determination, Postponement of Final Determination, and Extension of Provisional Measures,* 87 FR 28804 (May 11, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Commerce's Letter, ''Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from the Russian Federation: Verification of the Home Market and U.S. Sales Questionnaire Response of JSC Vyksa Steel Works and OMK Tube,'' dated July 15, 2022; *see also* Commerce's Letter, ''Verification of the Cost Response of Vyksa Steel Works in the Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from the Russian Federation,'' dated July 8, 2022. Commerce did not issue a similar request for documentation from the mandatory respondent, Volzhsky Pipe Plant, Joint Stock Company (VTZ), because VTZ withdrew its participation in this investigation subsequent to the *Preliminary Determination. See* VTZ/TMK's Letter, ''Antidumping Investigation of Oil Country Tubular Goods from Russia—VTZ and TMK Notice of Withdrawal from the Investigation,'' dated May 27, 2022.

Exporter or producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent) [4]
JSC Vyksa Steel Works	12.84	12.53
Volzhsky Pipe Plant, Joint Stock Company/Public Joint-Stock Company Trubnaya Metallurgicheskaya Kompaniya/Sinarsky Pipe Plant, Joint Stock Company/Seversky Pipe Plant, Joint Stock Company/Taganrog Metallurgical Plant, Joint Stock Company/Pervouralsk Pipe Plant, Joint Stock Company/Chelyabinsk Pipe Plant, Joint Stock Company/Orsky Machine Building Plant, Joint Stock Company [5]	* 184.21	* 184.21
All Others	12.84	12.70

* Adverse Facts Available (AFA).

Disclosure

We intend to disclose the calculations and analysis performed to interested parties in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend the liquidation of all appropriate entries of subject merchandise, as described in appendix I of this notice, entered, or withdrawn from warehouse, for consumption on or after May 11, 2022, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Section 735(c)(4)(B) of the Act provides that if there is an affirmative final determination of critical circumstances following a negative preliminary determination of critical circumstances, suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the date on which the suspension of liquidation was first ordered. As noted above, Commerce finds that critical circumstances exist for imports of subject merchandise produced and/or exported by TMK/VTZ. Therefore, in accordance with section 735(c)(4)(B) of the Act, suspension of liquidation shall apply to unliquidated entries of subject merchandise produced or exported by TMK/VTZ that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the date of publication of the *Preliminary Determination* in the **Federal Register**. These suspension of liquidation instructions will remain in effect until further notice.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rate for the companies listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a company identified above, but the producer is identified above, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of OCTG no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order

This notice will serve as a final reminder to the 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). Timely written notification of 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

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

[4] *See* Memoranda, ''Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from the Russian Federation: Final Determination Analysis Memorandum for JSC Vyksa Steel Works,'' dated concurrently with this memorandum; and ''Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from the Russian Federation: Final Determination Calculation for the All-Others,'' dated concurrently with this memorandum.

[5] Commerce preliminarily determined that Volzhsky Pipe Plant, Joint Stock Company; Public Joint-Stock Company Trubnaya Metallurgicheskaya Kompaniya; Sinarsky Pipe Plant, Joint Stock Company; Seversky Pipe Plant, Joint Stock Company; Taganrog Metallurgical Plant, Joint Stock Company; Pervouralsk Pipe Plant, Joint Stock Company; Chelyabinsk Pipe Plant, Joint Stock Company; Orsky Machine Building Plant, Joint Stock Company are affiliated within the meaning of 771(33)(F) of the Act, and should be treated as a single entity, in accordance with 19 CFR 351.401(f). *See Preliminary Determination; see also* Memorandum, ''Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from Russia: Preliminary Affiliation and Collapsing Memorandum for Volzhsky Pipe Plant,'' dated May 4, 2022. Commerce received no comments regarding the determination of affiliation among these companies. Accordingly, Commerce continues to find these companies are affiliated and continues to treat these companies as a single entity.

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of this investigation also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the OCTG.

Excluded from the scope of the investigation are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160, 7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to this investigation may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–21182 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–834]

Oil Country Tubular Goods From the Russian Federation: Final Affirmative Countervailing Duty Determination and Final Negative Critical Circumstances Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of oil country tubular goods (OCTG) from the Russian Federation (Russia). The period of investigation is January 1, 2020, through December 31, 2020.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Brontee George or Theodore Pearson, 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) 482–4645 or (202) 482–2631, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 14, 2022, Commerce published its *Preliminary Determination* [1] in the **Federal Register**. For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is made available to the public 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.*

Scope of the Investigation

The products covered by this investigation are oil country tubular goods from Russia. For a complete description of the scope of this investigation, *see* appendix I.

Scope Comments

On March 7, 2022, concurrent with the issuance of the *Preliminary Determination,* we issued a Preliminary Scope Decision Memorandum.[3] In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case briefs.[4] Commerce did not receive any comments from interested parties regarding the scope by the deadline. Consequently, we made no changes to the scope from the Preliminary Scope Decision Memorandum.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties

[1] *See Oil Country Tubular Goods from the Russia Federation: Preliminary Affirmative Countervailing Duty Determination, Preliminary Negative Critical Circumstances Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 87 FR 14249 (March 14, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Decision Memorandum for the Final Affirmative Determination in the Countervailing Duty Investigation of Oil Country Tubular Goods from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Antidumping Duty Investigations of Oil Country Tubular Goods from Argentina, Mexico, and the Russian Federation and Countervailing Duty Investigations of Oil Country Tubular Goods from the Republic of Korea, and the Russian Federation: Preliminary Scope Decision Memorandum,'' dated March 7, 2022 (Preliminary Scope Decision Memorandum).

[4] *Id.* at 4.

and addressed in the Issues and Decision Memorandum, *see* appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of AFA, *see* the *Preliminary Determination* and the section ''Use of Facts Otherwise Available and Application of Adverse Inferences'' in the accompanying Issues and Decision Memorandum.[6]

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of on-site verifications to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Act.[7]

Final Negative Determination of Critical Circumstances

Commerce determines that critical circumstances do not exist within the meaning of 703(e)(1) of the Act. For further information, *see* the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, as well as additional information collected in questionnaires issued subsequent to the *Preliminary Determination,* we made certain changes to the subsidy rate calculations for JSC Vyska Steel Works (collectively with its affiliated companies, OMK), Volzhsky Pipe Plant, Joint Stock Company (collectively with its affiliated companies, TMK Group), and the all-others rate. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the two mandatory respondents, OMK and TMK Group. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

We continue to calculate individual estimated countervailable subsidy rates for OMK and TMK Group that are not zero, *de minimis,* or based entirely on facts otherwise available. We, therefore, continue to calculate the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents (OMK and TMK Group) using each company's publicly-ranged sales value for their exports to the United States of subject merchandise,[8] in accordance with section 705(c)(5)(A)(i) of the Act.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Manufacturer/exporter	Subsidy rate (percent *ad valorem*)
Volzhsky Pipe Plant, Joint Stock Company; Sinarsky Pipe Plant, Joint Stock Company; Seversky Pipe Plant, Joint Stock Company; Taganrog Metallurgical Plant, Joint Stock Company; Orsky Machine Building Plant, Joint Stock Company; and PAO TMK[9]	1.30
JSC Vyksa Steel Works[10]	1.59
All Others	1.43

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d)(1)(B) and (d)(2) of the Act, we

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] *See Preliminary Determination* PDM at 8–13; *see also* Issues and Decision Memorandum at section ''Use of Facts Otherwise Available and Adverse Inferences.''

[7] *See* Commerce's Letters, ''Oil Country Tubular Goods from the Russian Federation: Volzhsky Pipe Plant, Joint Stock Company and Affiliated Companies Verification Questionnaire,'' dated May 11, 2022; and ''Oil Country Tubular Goods from the Russian Federation: Vyksa Steel Works and United Metallurgical Company (collectively, OMK) and Affiliated Companies Verification Questionnaire,'' dated May 11, 2022.

[8] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010); *see also Forged Steel Fluid End Blocks from Italy: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 85 FR 31460, 31461 (May 26, 2020), unchanged in *Forged Steel Fluid End Blocks from Italy: Final Affirmative Countervailing Duty Determination,* 85 FR 80022, 80023 (December 11, 2020).

[9] Commerce has found the following companies to be cross-owned with Volzhsky Pipe Plant, Joint Stock Company: TMK Neftegasservice-Nizhnevartovsk, Joint Stock Company; TMK Neftegasservice-Buzuluk, Limited Liability Company; Russian Research Institute of the Tube & Pipe Industries, JSC; and Scientific and Technical Center TMK, LLC.

[10] Commerce has found the following companies to be cross-owned with JSC Vyska Steel Works: BusinessOptima; Metallolomaya Company OMK—Ecometall; United Metallurgical Company; and Joint-Stock Company Trubodetal.

instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise from Russia that were entered, or withdrawn from warehouse, for consumption, on or after March 14, 2022, which is the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after July 12, 2022, but to continue the suspension of liquidation of all entries of subject merchandise between March 14 and July 11, 2022.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of OCTG from Russia. Because the final determination in this proceeding is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of OCTG from Russia no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of this investigation also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the OCTG.

Excluded from the scope of the investigation are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160,7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to this investigation may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–21179 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–119]

Antidumping Duty Order on Certain Large Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof From the People's Republic of China: Final Results of Changed Circumstances Review; Correction

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

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published a notice in the **Federal Register** of August 24, 2022, in which Commerce announced the final results of the changed circumstances review of the antidumping duty (AD) order on certain large vertical shaft engines between 225cc and 999cc, and parts thereof (vertical shaft engines) from the People's Republic of China (China). In this notice, Commerce inadvertently failed to apply the finding to subject merchandise produced and exported by Jialing-Honda Motors Co., Ltd (Jialing) or produced and exported by Honda Power Products (China) Co., Ltd. (Honda). In addition, Commerce did not include the term ''large'' in the heading of the notice.

FOR FURTHER INFORMATION CONTACT: Leo Ayala, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3945.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, Commerce published an amended final determination and antidumping duty order on vertical shaft engines from China.[1] In the *Order,* Commerce specified an estimated weighted-average dumping margin and cash deposit rate for merchandise produced and exported by Jialing-Honda Motors Co., Ltd (Jialing).[2] This cash deposit rate, a producer-exporter combination rate, is currently imposed for entries of subject merchandise produced and exported by Jialing.

On August 24, 2022, Commerce published in the **Federal Register** the final results of the changed circumstances review of the *Order* on vertical shaft engines from China.[3] In the *Final CCR Results,* Commerce found that Honda is the successor-in-interest to Jialing. However, Commerce incorrectly referenced the cash deposit rate for subject merchandise ''exported by Honda'' [4] instead of subject merchandise ''produced and exported by Honda.'' In addition, Commerce did not specify that the cash deposit rate for Jialing applied to subject merchandise produced and exported by Jialing.

Correction

In the **Federal Register** of August 24, 2022, in FR Doc 2022–18210 on page 51966, correct the heading of the notice to:

Antidumping Duty Order on Certain Large Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Final Results of Changed Circumstances Review; Correction.

On page 51966 in the third column, correct the first sentence of the second paragraph under the caption ''Final Results of Changed Circumstances Review'' to:

Consequently, Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced and exported by Honda and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at the AD cash deposit rate in effect for merchandise produced and exported by Jialing.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(b)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e).

Dated: September 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–21128 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Large Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof, from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty Order,* 86 FR 12623 (March 4, 2021) (*Order*).

[2] *Id.,* 86 FR at 12624.

[3] *See Antidumping Duty Order on Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Final Results of Changed Circumstances Review,* 87 FR 51966 (August 24, 2022) (*Final CCR Results*).

[4] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–848]

Emulsion Styrene-Butadiene Rubber From Mexico: Preliminary Results of the Antidumping Duty Administrative Review; 2020–2021

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that Industrias Negromex S.A. de C.V. (Negromex) did not make sales of emulsion styrene-butadiene rubber (ESB rubber) from Mexico at less than normal value during the period of review (POR) September 1, 2020, through August 31, 2021. We invite interested parties to comment on these preliminary results.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0413.

SUPPLEMENTARY INFORMATION:

Background

On September 12, 2017, Commerce published the antidumping duty order on ESB rubber from Mexico in the **Federal Register**.[1] On November 5, 2021, Commerce initiated an administrative review of the *Order,* in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] This review covers one producer/exporter of the subject merchandise, Negromex.

On May 19, 2022, Commerce extended the deadline for issuance of the preliminary results by 120 days, until September 30, 2022.[3] For a complete description of the events that followed the initiation of the review, *see* the Preliminary Decision Memorandum.[4]

[1] *See Emulsion Styrene-Butadiene Rubber from Brazil, the Republic of Korea, Mexico, and Poland: Antidumping Duty Orders,* 82 FR 42790 (September 12, 2017) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 61121 (November 5, 2021).

[3] *See* Memorandum, ''Emulsion Styrene-Butadiene Rubber from Mexico: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated May 19, 2022.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order: Emulsion Styrene-Butadiene Rubber from Mexico; 2020–2021,'' dated concurrently with, and hereby

Scope of the Order

The merchandise subject to the *Order* is ESB rubber from Mexico. For a complete description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. We have calculated constructed export price in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public 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 can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Review

For these preliminary results, Commerce has calculated an estimated weighted-average dumping margin for Negromex for the period September 1, 2020, through August 31, 2021, as follows:

Exporter/producer	Weighted-average dumping margin (percent)
Industrias Negromex S.A. de C.V	0.00

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If Negromex's weighted-average dumping margin is not zero or *de minimis* in the final results of this review, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales during the POR to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review where the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* If the respondent's weighted-average dumping margin is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[5]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Negromex for which the company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[6]

Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

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 the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Negromex will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for producers or exporters not covered in this review, but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 19.52 percent, the all-others rate established in the LTFV investigation.[7] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results.[8] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs 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 seven days after the date for filing case briefs.[9] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10] Case and rebuttal briefs should be filed using ACCESS,[11] and must be served on interested parties. Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[12]

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, within 30 days after the date of publication of this notice. An electronically-filed document must be received successfully in its entirety by 5:00 p.m. Eastern Time Hearing 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 respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[13] Parties should confirm

adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* section 751(a)(2)(C) of the Act.

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

[7] *See Order.*

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

[9] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

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

[11] *See* 19 CFR 351.303.

[12] *See Temporary Rule.*

[13] *See* 19 CFR 351.310(d).

the date, time, and location of the hearing two days before the scheduled date.

Final Results of Review

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

Notification to Importers

This notice also serves as a 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 POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

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

Dated: September 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–21130 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979, C–570–980]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Initiation of Changed Circumstances Reviews, and Consideration of Revocation of the Antidumping and Countervailing Duty Orders, in Part

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

SUMMARY: Based on a request from Shenzhen Hello Tech Energy Co., Ltd. (Hello Tech), the U.S. Department of Commerce (Commerce) is initiating changed circumstances reviews (CCR) to consider the possible revocation, in part, of the antidumping duty (AD) and countervailing duty (CVD) orders on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) with respect to certain off-grid small portable crystalline silicon photovoltaic (CSPV) panels as described below.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Daniel Alexander, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4313.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, Commerce published the AD and CVD orders on solar cells from China.[1] On August 8, 2022, Hello Tech, a Chinese producer and exporter of subject merchandise, requested, through CCRs, revocation of the *Orders,* in part, with respect to CSPV panels, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(b).[2] Within Hello Tech's CCR request, Hello Tech included a letter from the American Alliance for Solar Manufacturing (the Alliance), a U.S. producer of the domestic like product and a petitioner in the underlying investigations, in which the Alliance stated that it did not oppose the partial revocation of the *Orders* proposed by Hello Tech.[3] No interested parties filed comments opposing the CCR request.

Scope of the Orders

The merchandise covered by these *Orders* is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These *Orders* cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the *Orders.*

Excluded from the scope of the *Orders* are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS). Also excluded from the scope of the *Orders* are crystalline silicon photovoltaic cells, not exceeding 10,000mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the *Orders* are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the *Orders* are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics:

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012) (collectively, *Orders*).

[2] *See* Hello Tech's Letter, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules From the People's Republic of China: Hello Tech's Resubmitted Request for Changed Circumstances Reviews,'' dated August 8, 2022 (CCR Request).

[3] *Id.* at Exhibit 7.

(A) a total power output of 100 watts or less per panel;

(B) a maximum surface area of 8,000 cm^2 per panel;

(C) do not include a built-in inverter;

(D) must include a permanently connected wire that terminates in either an 8mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors;

(E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and

(F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics:

(A) a total power output of 100 watts or less per panel;

(B) a maximum surface area of 8,000 cm^2 per panel;

(C) do not include a built-in inverter;

(D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and

(E) each panel is

1. permanently integrated into a consumer good;

2. encased in a laminated material without stitching, or

3. has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the *Orders:* Off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water:

(A) A total power output of no more than 80 watts per panel;

(B) A surface area of less than 5,000 square centimeters (cm^2) per panel;

(C) Do not include a built-in inverter;

(D) Do not have a frame around the edges of the panel;

(E) Include a clear glass back panel; and

(F) Must include a permanently connected wire that terminates in a two-port rectangular connector.

Modules, laminates, and panels produced in a third country from cells produced in China are covered by the *Orders;* however, modules, laminates, and panels produced in China from cells produced in a third country are not covered by the *Orders.*

Merchandise covered by the *Orders* is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the *Orders* is dispositive.[4]

Proposed Partial Revocation of the Orders

The products subject to the proposed revocation are off-grid portable small crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics:

(A) total power output of 200 watts or less per panel;

(B) a maximum surface area of 16,000 cm^2 per panel;

(C) do not include a built-in inverter;

(D) must include an integrated handle or a handle attached to the package for ease of carry;

(E) must include one or more integrated kickstands for easy installation or angle adjustment; and

(F) must include a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8mm diameter male barrel connector.

Initiation of CCRs and Consideration of Revocation of the Orders, in Part

Pursuant to section 751(b) of the Act, when Commerce receives information concerning, or a request from an interested party [5] for a review of, a final affirmative determination that resulted in an AD or CVD order, which shows changed circumstances sufficient to warrant a review of an order, Commerce shall conduct a changed circumstances review of the order.[6] In accordance with 19 CFR 351.216(d), Commerce determines that the information submitted by Hello Tech, and the letter of no opposition to partial revocation of the *Orders* with respect to the products described by Hello Tech, constitute a sufficient basis to conduct CCRs of the *Orders*.[7]

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that Commerce may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. In addition, in the event that Commerce determines an expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits Commerce to combine the notices of initiation and preliminary results. In its administrative practice, Commerce has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[8]

One domestic producer, the Alliance, stated that it does not object to the partial revocation of the *Orders* proposed by Hello Tech. However, because the Alliance did not indicate whether it accounts for substantially all of the U.S. production of the domestic like product covered by the *Orders,* we are not combining this notice of initiation with a preliminary determination, pursuant to 19 CFR 351.221(c)(3)(ii). Rather, we will provide interested parties with an opportunity to address the issue of domestic industry support with respect to the partial revocation of the *Orders,* as explained below. After examining comments, if any, concerning domestic industry support, we will issue the preliminary results of these CCRs.

Public Comment

Interested parties are invited to provide comments and/or factual information regarding these CCRs, including comments on industry support and the proposed partial revocation language. Comments and factual information may be submitted to Commerce no later than fourteen days after the date of publication of this notice. Rebuttal comments and rebuttal factual information may be filed with Commerce no later than seven days after the comments and/or factual information are filed.[9] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[10] An electronically-filed document must be received successfully in its entirety by ACCESS, by 5 p.m.

[4] *See Orders.*

[5] Hello Tech stated in its CCR Request that it is an exporter of solar panels. As such, Hello Tech is an interested party pursuant to section 771(9)(A) of the Act and 19 CFR 351.102(b)(29)(i).

[6] *See* 19 CFR 351.216(d).

[7] *See* CCR Request at Exhibit 7.

[8] *See, e.g., Certain Cased Pencils from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent To Revoke Order in Part,* 77 FR 42276 (July 18, 2012), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination To Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

[9] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2).

[10] *See generally* 19 CFR 351.303.

Eastern Time on the due dates set forth in this notice. Note that Commerce has temporarily modified certain requirements for serving documents containing business proprietary information, until further notice.[11]

Preliminary and Final Results of the CCRs

Commerce intends to publish in the **Federal Register** a notice of the preliminary results of these AD and CVD CCRs in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice. Unless extended, Commerce will issue the final results of these CCRs in accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act and 19 CFR 351.221(b)(1).

Dated: September 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–21155 Filed 9–28–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–824]

Oil Country Tubular Goods From Argentina: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of oil country tubular goods (OCTG) from Argentina are being, or are likely to be, sold in the United States at less than fair value (LTFV) during the period of investigation, October 1, 2020, through September 30, 2021.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov, 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) 482–0665.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2022, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of OCTG from Argentina, in which it also postponed the final determination until September 23, 2022.[1] We invited interested parties to comment on the *Preliminary Determination.* A summary of the events that occurred since Commerce published the *Preliminary Determination* may be found in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is OCTG from Argentina. For a complete description of the scope of this investigation, *see* appendix I.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice at appendix II. 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.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, in June 2022, we took additional steps in lieu of on-site verifications to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, Commerce performed virtual verifications of the cost of production response, home market and U.S. sales responses, as well as a further-manufacturing cost response.[3]

Changes Since the Preliminary Determination

Based on our analysis of the comments received, we made certain changes to the margin calculations for this final determination. For a discussion of these changes, *see* the ''Changes from the Preliminary Determination'' section of the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act (*i.e.,* facts otherwise available). Commerce calculated an individual estimated weighted-average dumping margin for Siderca S.A.I.C. (Siderca), the only individually examined producer or exporter in this investigation. Because the only individually calculated estimated weighted-average dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for all other producers and/or exporters is equal to the estimated weighted-average dumping margin calculated for the single examined respondent, Siderca, pursuant to section 735(c)(5)(A) of the Act.

Final Negative Determination of Critical Circumstances

In accordance with section 735(a)(3) of the Act and 19 CFR 351.206(h), Commerce finds that critical

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[1] *See Oil Country Tubular Goods from Argentina: Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 87 FR 28801 (May 11, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from Argentina, and Final Negative Determination of Critical Circumstances,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memoranda, ''Verification of the Sales Questionnaire Response of Siderca S.A.I.C. in the Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from Argentina,'' dated June 30 2022; ''Verification of the Sales Questionnaire Response of Tenaris Global Services (U.S.A.) Corporation in the Less-Than-Fair-Value Investigation of Oil Country Tubular Goods from Argentina,'' dated June 30, 2022; ''Virtual Verification of the Further Manufacturing Cost Response of Siderca S.A.I.C. in the Antidumping Duty Investigation of Oil Country Tubular Goods from Argentina,'' dated July 28, 2022; and ''Virtual Verification of the Cost of Manufacturing Response of Siderca S.A.I.C. in the Antidumping Duty Investigation of Oil Country Tubular Goods from Argentina,'' dated July 28, 2022.

circumstances do not exist for all companies in Argentina. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the ''Final Negative Determination of Critical Circumstances'' section of the Issues and Decision Memorandum.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margin (percent)
Siderca S.A.I.C	78.30
All Others	78.30

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue the suspension of liquidation of all appropriate entries of subject merchandise, as described in appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 11, 2022, the date of publication of the *Preliminary Determination* in this investigation in the **Federal Register**. These suspension of liquidation instructions will remain in effect until further notice.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rate for the companies listed above will be equal to the respondent-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a company identified above but the producer is identified above, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

As noted above, Commerce finds that critical circumstances do not exist for imports of OCTG from Argentina produced and exported by all companies. In accordance with section 735(c)(3) of the Act, Commerce will instruct CBP to terminate any retroactive suspension of liquidation required under section 733(e)(2) of the Act, and release any bond or other security, and refund any cash deposit required, under section 733(d)(1)(B) of the Act, with respect to entries of the merchandise the liquidation of which was suspended retroactively under section 733(e)(2) of the Act before May 11, 2022.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of OCTG no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Suspension of Liquidation'' section.

Administrative Protective Order

This notice will serve as a final reminder to the parties subject to 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). 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 sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of this investigation also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the OCTG.

Excluded from the scope of the investigation are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160,7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to this investigation may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000,

7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–21184 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–913]

Oil Country Tubular Goods From the Republic of Korea: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of oil country tubular goods (OCTG) from the Republic of Korea (Korea). The period of investigation is January 1, 2020, through December 31, 2020.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Jacob Garten or Melissa Porpotage, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3342 or (202) 482–1413, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 14, 2022, Commerce published the *Preliminary Determination* in the **Federal Register**.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2] 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.*

Scope of the Investigation

The products covered by this investigation are OCTG from Korea. For a complete description of the scope of this investigation, *see* appendix I.

Scope Comments

On March 7, 2022, concurrent with the issuance of the *Preliminary Determination,* we issued a Preliminary Scope Memorandum.[3] In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case briefs.[4] Commerce did not receive any comments from interested parties regarding the scope by the deadline. Consequently, we made no changes to the scope from the Preliminary Scope Decision Memorandum.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and to which we responded in the Issues and Decision Memorandum, *see* appendix II of this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient and that the subsidy is specific.[5] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of AFA, *see* the section ''Use of Facts Available and Adverse Inferences'' in the accompanying Issues and Decision Memorandum.

Verification

As provided in section 782(i) of the Act, in August 2022, Commerce verified the subsidy information reported by Hyundai Steel Company (Hyundai Steel),[6] SeAH Steel Corporation (SeAH Steel), and the Government of Korea. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by the respondents.

Changes Since the Preliminary Determination

Based on our review and analysis of the information received at verification and comments received from parties, we made certain changes to the subsidy rate calculations for Hyundai Steel and SeAH Steel. As a result of these changes, Commerce also revised the all-others rate. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we calculated an individual estimated countervailable subsidy rate for the two mandatory respondents, Hyundai Steel and SeAH Steel. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal

[1] *See Oil Country Tubular Goods from the Republic of Korea: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 87 FR 14248 (March 14, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Decision Memorandum for the Final Determination of the Countervailing Duty Investigation of Oil Country Tubular Goods from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Antidumping Duty Investigations of Oil Country Tubular Goods from Argentina, Mexico, and the Russian Federation and Countervailing Duty Investigations of Oil Country Tubular Goods from the Republic of Korea, and the Russian Federation: Preliminary Scope Decision Memorandum,'' dated March 7, 2022 (Preliminary Scope Memorandum).

[4] *Id.* at 4.

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] Hyundai Steel Company is the same respondent from the *Preliminary Determination,* where we incorrectly stated the company's name as Hyundai Steel Corporation.

to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

In this investigation, Commerce calculated a *de minimis* rate for Hyundai Steel. Therefore, the only rate that is not zero, *de minimis,* or based entirely on facts otherwise available is the rate calculated for SeAH Steel. Consequently, the rate calculated for SeAH Steel is also assigned as the rate for all other producers and exporters.

Final Determination

Commerce determines that the following estimated net countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
Hyundai Steel Company	0.25 (*de minimis*).
SeAH Steel Corporation [7]	1.33.
All Others	1.33.

Disclosure

Commerce intends to disclose to interested parties its calculations performed in this final determination within five days of any public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination,* the total net countervailable subsidy rates for the individually examined respondents were *de minimis,* and, therefore, we did not suspend liquidation of entries of OCTG from Korea. However, as the estimated subsidy rate for one examined company, SeAH Steel, as well as the all-others rate is above *de minimis* in this final determination, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of OCTG from Korea, other than those produced and exported by Hyundai Steel Company, that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above, pursuant to section 705(c)(1)(B)(ii) of the Act. The suspension of liquidation will remain in effect until further notice.

[7] As discussed in the Preliminary Decision Memorandum, Commerce has found the following company to be cross-owned with SeAH Steel Corporation: SeAH Steel Holding Corporation.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above, in accordance with section 706(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of OCTG from Korea. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of OCTG from Korea. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to the APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 771(i) of the Act, and 19 CFR 351.210(c).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of this investigation also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the OCTG.

Excluded from the scope of the investigation are: Casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160, 7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to this investigation may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–21181 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–846]

Certain Steel Nails From the Republic of Turkey: Postponement of Final Determination of Sales at Less Than Fair Value Investigation

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

SUMMARY: The U.S. Department of Commerce (Commerce) is postponing the deadline for issuing the final determination in the less-than-fair-value (LTFV) investigation of certain steel nails (nails) from the Republic of Turkey (Turkey) until December 19, 2022, and is extending the provisional measures from a four-month period to a period of not more than six months.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3693.

SUPPLEMENTARY INFORMATION:

Background

On January 19, 2022, Commerce initiated an LTFV investigation of imports of nails from Turkey.[1] The period of investigation is October 1, 2020, through September 30, 2021. On August 4, 2022, Commerce published the *Preliminary Determination*.[2]

Postponement of Final Determination

Section 735(a)(2) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(2) provide that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by the exporters or producers who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Further, 19 CFR 351.210(e)(2) requires that such postponement requests by exporters be accompanied by a request for extension of provisional measures from a four-month period to a period of not more than six months, in accordance with section 733(d) of the Act.

On August 2, 2022, Aslanbas Civi Tel Ve Celik Hasir San. A.S. (Aslanbas) and Sertel Vida Metals, A.S. (Sertel Vida), mandatory respondents in this investigation, requested that Commerce postpone the deadline for the final determination until no later than 135 days from the publication of the *Preliminary Determination,* and extend the application of the provisional measures from a four-month period to a period of not more than six months.[3] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination was affirmative; (2) the request was made by the exporters and producers who account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination until no later than 135 days after the date of the publication of the *Preliminary Determination,* and extending the provisional measures from a four-month period to a period of not more than six months. Accordingly, Commerce will issue its final determination no later than December 19, 2022.[4]

This notice is issued and published pursuant to 19 CFR 351.210(g).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–21132 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Steel Nails from India, Sri Lanka, Thailand, and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 87 FR 3965 (January 26, 2022).

[2] *See Certain Steel Nails from the Republic of Turkey: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 87 FR 47699 (August 4, 2022) (*Preliminary Determination*).

[3] *See* Aslanbas and Sertel Vida's Letter, ''Request to Extend the Final Determination,'' dated August 2, 2022.

[4] Postponing the final determination to 135 days after the publication of the *Preliminary Determination* would place the deadline on Saturday, December 17, 2022. Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–073]

Common Alloy Aluminum Sheet From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2020–2021; Correction

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

ACTION: Notice; correction.

SUMMARY: On September 8, 2022, the U.S. Department of Commerce (Commerce) published the **Federal Register** notice of the final results of the administrative review of the antidumping duty order on common alloy aluminum sheet from the People's Republic of China (China) covering the period February 1, 2020, through January 31, 2021. That notice incorrectly identified the name of one company in the final results of the review rate table.

FOR FURTHER INFORMATION CONTACT: Frank Schmitt, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4880.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 8, 2022, FR Doc. 2022–19342, on page 54976, in the weighted-average dumping margin table, make the following correction:

• In the first row of the ''Exporter'' column, revise the first-listed company name, ''Jiangsu Alcha Aluminum Co., Ltd.'' to ''Jiangsu Alcha Aluminum Group Co., Ltd.''

Background

On September 8, 2022, Commerce published in the **Federal Register** the final results of the administrative review of the antidumping duty order on common alloy aluminum sheet from China covering the period February 1, 2020, through January 31, 2021.[1]

In the weighted-average dumping margin table, Commerce inadvertently misidentified Jiangsu Alcha Aluminum Group Co., Ltd., as Jiangsu Alcha Aluminum Co., Ltd. (omitting the word ''Group'' between ''Aluminum'' and ''Co.'').

The corrected weighted-average dumping margin table is as follows:

Exporter	Weighted-average dumping margin (percent)
Jiangsu Alcha Aluminum Group Co., Ltd.[2]/Baotou Alcha Aluminum Co., Ltd./Alcha International Holdings Limited	51.50
Non-Selected Company Under Review Receiving a Separate Rate	
Yinbang Clad Material Co., Ltd ..	51.50

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1), 751(a)(2)(B), and 777(i)(1) of the Tariff Act of 1930 as amended, and 19 CFR 351.221(b)(5).

Dated: September 23, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–21131 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–124, C–570–125]

Certain Vertical Shaft Engines Between 99cc and Up To 225cc, and Parts Thereof, From the People's Republic of China: Affirmative Preliminary Determination of Circumvention of the Antidumping and Countervailing Duty Orders—Dual-Piston Engines; Rescission in Part

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that imports of dual-piston engines with a single, common combustion chamber, of the type designed by FNA Group, Inc. (FNA), produced in and exported from the People's Republic of China (China) constitute later-developed merchandise that circumvent the antidumping duty (AD) and countervailing duty (CVD) orders on certain vertical shaft engines between 99cc and up to 225cc, and parts thereof (small vertical engines), from China. Commerce also preliminarily determines that this affirmative circumvention finding should be applied on a country-wide basis.

DATES: Applicable September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Paul Gill, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5673.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 2021, Commerce published AD and CVD orders on small vertical engines from China.[1] On April 25, 2022, in response to a request from Briggs & Stratton, LLC (the petitioner), Commerce initiated a circumvention inquiry to determine whether dual-piston engines with a single, common combustion chamber, of the type designed by FNA, involve a ''minor alteration'' to subject merchandise or are ''later-developed merchandise,'' such that they should be considered subject to the AD and CVD orders on small vertical engines from China.[2] The petitioner alleges that such merchandise, produced in, and exported from, China, and imported into the United States may circumvent the *Orders*. For a complete description of the events that followed the initiation of this inquiry, *see* the Preliminary Decision Memorandum.[3]

Scope of the Orders

The products subject to the *Orders* are small vertical engines from China. For a complete description of the scope of the *Orders, see* the Preliminary Decision Memorandum.[4]

Merchandise Subject to the Circumvention Inquiry

The merchandise subject to this circumvention inquiry are dual-piston engines with a single, common

[1] *See Common Alloy Aluminum Sheet from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2020–2021,* 87 FR 54975 (September 8, 2022).

[2] For the purposes of this review, we have considered the names Jiangsu Alcha Aluminum Group Co., Ltd. and Jiangsu Alcha Aluminium Group Co., Ltd. as equivalent.

[1] *See Certain Vertical Shaft Engines Between 99cc and Up To 225cc, and Parts Thereof from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 86 FR 23675 (May 4, 2021) (*Orders*).

[2] *See Certain Vertical Shaft Engines Between 99cc and Up To 225cc, and Parts Thereof, from the People's Republic of China: Initiation of Circumvention Inquiry of the Antidumping and Countervailing Duty Orders—Dual-Piston Engines,* 87 FR 24280 (April 25, 2022) (*Initiation Notice*); *see also* Petitioner's Letter, ''Request for Anti-Circumvention Inquiry Pursuant to section 781(c) and/or 781(d) of the Tariff Act of 1930,'' dated March 4, 2022.

[3] *See* Memorandum, ''Certain Vertical Shaft Engines Between 99cc and Up To 225cc from the People's Republic of China: Preliminary Decision Memorandum for Circumvention Inquiry—Dual-Piston Engines,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *Id.* at 2–3.

combustion chamber, of the type designed by FNA, otherwise meeting the scope of the *Orders*. In the *Initiation Notice,* Commerce used the term ''dual-piston engine'' to refer to the engines subject to this inquiry, such as FNA's dual-piston engine. More specifically, the dual-piston engines subject to this circumvention inquiry have a common combustion chamber shared by two cylinders working in unison.[5] For a complete description of the inquiry merchandise, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this circumvention inquiry pursuant to section 781(d) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.226(k). For a complete description of the events that followed the initiation of this circumvention inquiry, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as the appendix 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 can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Affirmative Preliminary Determination of Circumvention

As detailed in the Preliminary Decision Memorandum, Commerce preliminarily determines that imports of dual-piston engines with a single, common combustion chamber, of the type designed by FNA, produced in and exported from China constitute later-developed merchandise that circumvent the *Orders,* pursuant to section 781(d) of the Act and 19 CFR 351.226(k). We also preliminarily determine that this affirmative circumvention finding should be applied on a country-wide basis.

Partial Rescission

Commerce initiated this inquiry pursuant to sections 781(c) and (d) of the Act.[6] However, because we preliminarily determine that dual-piston engines with a single, common combustion chamber, of the type designed by FNA, are later-developed merchandise that are circumventing the *Orders,* pursuant to section 781(d) of the Act, Commerce is not evaluating whether the inquiry merchandise was also ''altered in form or appearance in minor respects'' in an attempt to circumvent the *Orders,* pursuant to 19 CFR 351.226(j) and section 781(c) of the Act. Therefore, we are rescinding the prong of this circumvention inquiry pertaining to section 781(c) of the Act.

Suspension of Liquidation

In accordance with 19 CFR 351.226(l)(2), we will direct U.S. Customs and Border Protection (CBP) to continue the suspension of liquidation of previously suspended entries and to suspend liquidation of all entries of dual-piston engines with a single, common combustion chamber, of the type designed by FNA, produced in and exported from China that are entered, or withdrawn from warehouse, for consumption on or after April 25, 2022 (*i.e.,* the date of the publication of the *Initiation Notice*).[7] Pursuant to 19 CFR 351.226(l)(2), we will also instruct CBP to require cash deposits of estimated ADs and CVDs equal to the cash deposit rates in effect for small vertical engines for each unliquidated entry of dual-piston engines with a single, common combustion chamber, of the type designed by FNA, produced in and exported from China that have been entered, or withdrawn from warehouse, for consumption on or after April 25, 2022.[8] These suspension of liquidation instructions and cash deposit requirements will remain in effect until further notice.

Public Comments

Interested parties are invited to comment on this preliminary determination of circumvention and may submit case briefs or other written comments within 30 days of the date of publication of this notice.[9] Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline for case briefs.[10] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this circumvention inquiry are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11] Case and rebuttal briefs should be filed electronically via ACCESS.[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of the issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the date and time for the hearing at a later date.

All submissions must be filed electronically and received successfully in its entirety via ACCESS by 5:00 p.m. Eastern Time on the date that they are due. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[13]

Notification to Interested Parties

This determination is published in accordance with section 781(d) of the Act and 19 CFR 351.226(f) and (k).

Dated: September 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–21127 Filed 9–28–22; 8:45 am]

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[5] *See* Petitioner's Letter, ''Request for Anti-Circumvention Inquiry Pursuant to Section 781(c) and/or Section 781(d) of the Tariff Act of 1930,'' dated March 4, 2022, at 2–3.

[6] *See Initiation Notice,* 87 FR at 24280–81.

[7] *Id.*

[8] *See Orders.*

[9] Commerce is exercising its discretion, under 19 CFR 351.309(c)(1)(ii), to alter the time limit for filing of case briefs.

[10] Commerce is exercising its discretion, under 19 CFR 351.309(d)(1), to alter the time limit for filing of rebuttal briefs.

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

[12] *See* 19 CFR 351.303.

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC092

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the Atlantic Shores Offshore Wind Energy Projects Offshore of New Jersey

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

ACTION: Notice; receipt of application for Letters of Authorization; request for comments and information.

SUMMARY: NMFS has received a request from Atlantic Shores Offshore Wind, LLC (Atlantic Shores) for authorization to take small numbers of marine mammals incidental to activities associated with two offshore wind energy projects in the Bureau of Ocean Energy Management's (BOEM) Lease Area Outer Continental Shelf (OCS)–A–0499 off of New Jersey over the course of 5 years beginning on January 1, 2025. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of Atlantic Shores' request for the development and implementation of regulations governing the incidental taking of marine mammals and associated Letters of Authorization (LOAs). NMFS invites the public to provide information, suggestions, and comments on Atlantic Shores' application and request.

DATES: Comments and information must be received no later than October 31, 2022.

ADDRESSES: Comments on the applications should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Potlock@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 received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or 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: Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427–8401. An electronic copy of Atlantic Shores' application 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

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 issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An incidental take authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On February 28, 2022, NMFS received an application from Atlantic Shores requesting authorization to take marine mammals incidental to construction activities associated with two offshore wind energy projects (referred to as Project 1 and Project 2 in the application) in the Lease Area OCS–A–0499 off of New Jersey. In response to our comments, and following extensive information exchanges with NMFS, Atlantic Shores submitted a revised application on August 12, 2022, that we determined was adequate and complete on August 25, 2022. The requested regulations would be valid for 5 years, from January 1, 2025 through December 31, 2029.

Atlantic Shores plans to conduct construction activities for Projects 1 and 2 that consist of the following: impact installation of wind turbine generator (WTG) and offshore substation (OSS) foundations (consisting of either monopile or jacket foundations); site characterization surveys; impact installation of a permanent meteorological (met) tower; deployment of metocean buoys; placement of scour protection; the installation of eight export cables via trenching, laying, and burial; and vibratory pile driving to temporarily install and remove sheet pile cofferdams at two cable landfall sites. Vessels will be used to transport crew, supplies, and materials to the project area and to support construction activities. Atlantic Shores may also conduct fisheries surveys during the effective period of the requested regulations, as required by BOEM. Atlantic Shores has indicated no unexploded ordinance/munitions and explosives of concern (UXO/MEC) detonations would occur during the effective period of the regulations and has not included this activity as part of the specified activities. A subset of the specified activities included in the application (*i.e.,* installing piles using impact and vibratory pile driving and site characterization surveys) may result in the incidental take, by Level A harassment and/or Level B harassment, of marine mammals. Therefore, Atlantic Shores requests authorization to incidentally take marine mammals.

Specified Activities

In Executive Order 14008, President Biden stated that it is the policy of the

United States to organize and deploy the full capacity of its agencies to combat the climate crisis to implement a Government-wide approach that reduces climate pollution in every sector of the economy; increases resilience to the impacts of climate change; protects public health; conserves our lands, waters, and biodiversity; delivers environmental justice; and spurs well-paying union jobs and economic growth, especially through innovation, commercialization, and deployment of clean energy technologies and infrastructure.

Through a competitive leasing process under 30 CFR 585.211, Atlantic Shores was award Commercial Lease OCS–A 0499, located offshore of New Jersey in the New Jersey Wind Energy Area and has the exclusive rights to submit a construction and operations plan (COP) for activities within the lease area. Atlantic Shores has submitted a COP to BOEM proposing the construction, operation, maintenance, and conceptual decommissioning of Project 1 and Project 2, collectively generating 1,510 megawatts (MW) of clean energy. Combined, these projects will have a maximum of 200 WTGs, 10 OSSs, 1 meteorological tower, and 8 transmission cables making landfall at 2 locations in Atlantic and Monmouth Counties.

Atlantic Shores anticipates that activities potentially resulting in the take of marine mammals could occur during the life of the requested regulations and associated 5-year Letters of Authorization (LOAs). Specifically, these activities are:

- The installation, via impact pile driving, of up to 200 WTGs utilizing either monopile (up to 15-meter (m) in diameter) or jacket foundations (up to 5-m in diameter pin piles). Project 1 would be comprised of 105–111 foundations and Project 2 would be comprised of 89–95 foundations;
- The installation, via impact driving, of up to 10 OSSs using up to jacket foundations comprised of 5-m pin piles (with 5 OSSs allocated to each project);
- Construction-related high-resolution site assessment geophysical surveys utilizing acoustic sources with frequencies of <180 kilohertz (kHz) for up to 300 days (estimate of 60 days annually) during all 5 years;
- The installation, via impact driving, of one permanent met tower in Project 1 using either a monopile up to 15-m in diameter or a jacket foundation using up to 5-m pin piles; and
- The installation and removal, via vibratory driving, of up to eight temporary steel sheet pile cofferdams at the Atlantic cable landfall site (Project 1) and the Monmouth cable landfall site (Project 2).

Information Solicited

Interested persons may submit information, suggestions, and comments concerning Atlantic Shores' request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the request during the development of proposed regulations governing the incidental taking of marine mammals by Atlantic Shores, if appropriate.

Dated: September 23, 2022.

Kimberly Damon-Randall,

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

[FR Doc. 2022–21104 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Program; Notice of Public Meeting; Request for Comments

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of public meeting and opportunity to comment.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management, will hold a public meeting to solicit comments on the performance evaluation of the Ohio Coastal Management Program.

DATES: NOAA will consider all written comments received by Friday, October 28, 2022. A public meeting will be held on Wednesday, October 19, 2022, at 4 p.m. eastern daylight time (EDT).

ADDRESSES: Comments may be submitted by one of the following methods:

Email: Ralph Cantral, Evaluator, NOAA Office for Coastal Management, at *Ralph.Cantral@noaa.gov.*

Written comments received are considered part of the public record, and the entirety of the comment, including the name of the commenter, email address, attachments, and other supporting materials, will be publicly accessible. Sensitive personal information, such as account numbers or Social Security numbers, should not be included with the comment. Comments that are not responsive or that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.

Public Meeting: Provide oral comments during the virtual public meeting on Wednesday, October 19, 2022, at 4 p.m. EDT by registering as a speaker at *https://forms.gle/yCaey6vciCKGMKTo7.* Please register by Tuesday, October 18, 2022, at 5 p.m. EDT. Upon registration, a confirmation email will be sent. The lineup of speakers will be based on the date and time of registration. One hour prior to the start of the meeting on October 19, 2022, an email will be sent out with a link to the public meeting and information about participating.

FOR FURTHER INFORMATION CONTACT: Ralph Cantral, Evaluator, NOAA Office for Coastal Management, by email at *Ralph.Cantral@noaa.gov* or by phone at (843) 474–1357. Copies of the previous evaluation findings and the 2016–2020 Assessment and Strategies may be viewed and downloaded on the internet at *http://coast.noaa.gov/czm/evaluations/.* A copy of the evaluation notification letter and most recent progress report may be obtained upon request by contacting Ralph Cantral.

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally approved coastal management programs and national estuarine research reserves. The evaluation process includes holding one or more public meetings, considering written public comments, and consulting with interested Federal, State, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the State of Ohio has met the national objectives, adhered to the management program approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is complete, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the final evaluation findings.

Keelin Kuipers,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–21136 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC409]

Marine Mammals; File No. 26593

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Adam Pack, Ph.D., University of Hawaii at Hilo, 200 West Kawili Street, Hilo, HI 96720, has applied in due form for a permit to conduct research on humpback whales (*Megaptera novaeangliae*) and other cetaceans.

DATES: Written, telefaxed, or email comments must be received on or before October 31, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 26593 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26593 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Courtney Smith, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to study 29 cetacean species in Hawaiian and Alaskan waters, with a focus on humpback whales. The purpose of the research is to examine the behavioral ecology, biology and communication systems of humpback whales as well as the abundance, distribution, behavior, and physiological stress levels of all cetacean species in the study area. Research would be conducted from boats, airplanes, unmanned aircraft systems, and underwater. Animals would be studied using photo-ID, videogrammetry, passive acoustic recordings, behavioral observations, collection of fecal and skin samples, and biopsy sampling. In addition, up to 150 video and acoustic recording suction cup tags would be deployed on humpback whales, annually. Threatened and endangered species that would be studied if encountered are: blue (*Balaenoptera musculus*), bowhead (*Balaena mysticetus*), false killer (*Pseudorca crassidens*) (Main Hawaiian Islands Insular distinct population segment (DPS)), fin (*B. physalus*), humpback (Central America and Mexico DPSs), North Pacific right (*Eubalaena japonica*), sei (*B. borealis*), and sperm whales (*Physeter macrocephalus*). The permit would be valid for 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 26, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–21134 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0053]

Grant of Interim Extension of the Term of U.S. Patent No. 6,406,699; ECI® (ELIAS Cancer Immunotherapy)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 6,406,699 ('699 patent).

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7728 or *raul.tamayo@uspto.gov.*

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On September 6, 2022, TVAX Biomedical I, LLC, the owner of record of the '699 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a fourth interim extension of the term of the '699 patent. The '699 patent claims a method of using a veterinary biological product in the cancer immunotherapy treatment known by the tradename ECI® (ELIAS Cancer Immunotherapy). The application for interim patent term extension indicates that a RRP as described in 35 U.S.C. 156(g)(5)(B)(ii) began for ECI® (ELIAS Cancer Immunotherapy) and is ongoing before the United States Department of Agriculture, Center for Veterinary Biologics, for permission to market and use the product commercially.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '699 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it is apparent that the RRP will continue beyond the thrice-extended expiration date of the '699 patent, *i.e.,* October 5, 2022, a fourth interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fourth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 6,406,699 is granted for a period of one year from the thrice-extended expiration date of the '699 patent.

Robert Bahr,

Deputy Commissioner for Patents, United States Patent and Trademark Office.

[FR Doc. 2022–21118 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0052]

Grant of Interim Extension of the Term of U.S. Patent No. 7,199,162; Grafapex™ (Treosulfan)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 7,199,162 ('162 patent).

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7728 or *raul.tamayo@uspto.gov.*

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On August 25, 2022, Medac Gesellschaft fuer Klinische Spezialpraparate M.B.H., the owner of record of the '162 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a second interim extension of the term of the '162 patent. The '162 patent claims a method of using the human drug product known by the tradename GRAFAPEX™ (treosulfan). The application for interim patent term extension indicates that a RRP as described in 35 U.S.C. 156(g)(1)(B)(ii) began for GRAFAPEX™ (treosulfan) and is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '162 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it is apparent that the RRP will continue beyond the once-extended expiration date of the '162 patent, *i.e.,* October 12, 2022, a second interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,199,162 is granted for a period of one year from the once-extended expiration date of the '162 patent.

Robert Bahr,

Deputy Commissioner for Patents, United States Patent and Trademark Office.

[FR Doc. 2022–21117 Filed 9–28–22; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (''PRA''), this notice announces that the Information Collection Request (''ICR'') abstracted below has been forwarded to the Office of Information and Regulatory Affairs (''OIRA''), of the Office of Management and Budget (''OMB''), for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before October 31, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of this notice's publication to OIRA, at *https://www.reginfo.gov/public/do/PRAMain.* Please find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the website's search function. Comments can be entered electronically by clicking on the ''comment'' button next to the information collection on the ''OIRA Information Collections Under Review'' page, or the ''View ICR—Agency Submission'' page. A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting *https://www.reginfo.gov/public/do/PRAMain.*

In addition to the submission of comments to *https://Reginfo.gov* as indicated above, a copy of all comments submitted to OIRA may also be submitted to the Commodity Futures Trading Commission (the ''Commission'' or ''CFTC'') by clicking on the ''Submit Comment'' box next to the descriptive entry for OMB Control No. 3038–0067, at *https://comments.cftc.gov/FederalRegister/PublicInfo.aspx.*

Or by either of the following methods:

- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments submitted to the Commission should include only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1] The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Andrew Chapin, Associate Chief Counsel, Market Participants Division, Commodity Futures Trading Commission, (202) 418–5465; email: *achapin@cftc.gov,* and refer to OMB Control No. 3038–0067.

SUPPLEMENTARY INFORMATION:

Title: Part 162—Protection of Consumer Information under the Fair Credit Reporting Act (OMB Control No. 3038–0067). This is a request for extension of a currently approved information collection.

Abstract: On July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'').[2] Title X of the Dodd-Frank Act, which is titled the Consumer Financial Protection Act of 2010 (''CFP Act''), amends a number of federal consumer protection laws enacted prior to the Dodd-Frank Act including, in relevant part, the Fair Credit Reporting Act

[1] 17 CFR 145.9.

[2] Pub. L. 111–203, 124 Stat. 1376 (2010).

(''FCRA'') [3] and the Fair and Accurate Credit Transactions Act of 2003 (''FACT Act'').[4] Specifically, Section 1088 of the CFP Act sets out certain amendments to the FCRA and the FACT Act directing the Commission to promulgate regulations that are intended to provide privacy protections to certain consumer information held by an entity that is subject to the jurisdiction of the Commission.

Section 1088 amends section 214(b) of the FACT Act—which added section 624 to the FCRA in 2003—and directs the Commission to implement the provisions of section 624 of the FCRA with respect to persons that are subject to the Commission's enforcement jurisdiction. Section 624 of the FCRA gives a consumer the right to block affiliates of an entity subject to the Commission's jurisdiction from using certain information obtained from such entity to make solicitations to that consumer (hereinafter referred to as the ''affiliate marketing rules'').[5] Under the affiliate marketing rules, the entities covered by the regulations are expected to prepare and provide clear, conspicuous and concise opt-out notices to any consumers with whom such entities have a pre-existing business relationship. A covered entity only has to provide an opt-out notice to the extent that an affiliate of the covered entity plans to make a solicitation to any of the covered entity's consumers. The purpose of the opt-out notice is to provide consumers with the ability to prohibit marketing solicitations from affiliate businesses that do not have a pre-existing business relationship with the consumers, but that do have access to such consumers' nonpublic, personal information. A covered entity is required to send opt-out notices at the maximum of once every five years.

Section 1088 of the CFP Act also amends section 628 of the FCRA and mandates that the Commission implement regulations requiring persons subject to the Commission's jurisdiction who possess or maintain consumer report information in connection with their business activities to properly dispose of that information (hereinafter referred to as the ''disposal rules'').[6] Under the disposal rules, the entities covered by the regulations are expected to develop and implement a written disposal plan with respect to any consumer information within such entities' possession. The regulations provide that a covered entity develop a written disposal plan that is tailored to the size and complexity of such entity's business. The purpose of the written disposal plan is to establish a formal plan for the disposal of nonpublic, consumer information, which otherwise could be illegally confiscated and used by unauthorized third parties. Under the rules, a covered entity is required to develop a written disposal plan only once, but may subsequently amend such plan from time to time.

In addition, section 1088 of the CFP Act amended the FCRA by adding the CFTC and the Securities and Exchange Commission (''SEC,'' together with the CFTC, the ''Commissions'') to the list of federal agencies required to jointly prescribe and enforce identity theft red flags rules and guidelines and card issuer rules. Thus, the Dodd-Frank Act provides for the transfer of rulemaking responsibility and enforcement authority to the CFTC and SEC with respect to the entities under their respective jurisdiction. Accordingly, the Commissions have issued final rules and guidelines (hereinafter referred to as the ''identity theft rules'') [7] to implement new statutory provisions enacted by the CFP Act that amend section 615(e) of the FCRA and direct the Commissions to prescribe rules requiring entities that are subject to the Commissions' jurisdiction to address identity theft. Under the identity theft rules, entities covered by the regulation are required to develop and implement reasonable policies and procedures to identify, detect, and respond to relevant red flags for identity theft that are appropriate to the size and complexity of such entity's business and, in the case of entities that issue credit or debit cards, to assess the validity of, and communicate with cardholders regarding, address changes.[8] They are also required to provide for the continued administration of identity theft policies and procedures.

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. On July 22, 2022, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 87 FR 43797 (''60-Day Notice''). The Commission did not receive any relevant comments on the 60-Day Notice.

Burden Statement: The Commission is revising its burden estimate for this collection to reflect its estimate of the current number of CFTC registrants subject to the requirements of part 162 regulations. The respondent burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 4,420.

Estimated Total Annual Burden Hours: 58,090.

Frequency of Collection: As applicable.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: September 26, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2022–21103 Filed 9–28–22; 8:45 am]

BILLING CODE 6351–01–P

[3] 15 U.S.C. 1681–1681x.

[4] Public Law 108–159, 117 Stat. 1952, 1980 (2003).

[5] The affiliate marketing rules are found in part 162, subpart A (Business Affiliate Marketing Rules) of the CFTC's regulations. 17 CFR part 162, subpart A.

[6] The disposal rules are found in part 162, subpart B (Disposal Rules) of the CFTC's regulations. 17 CFR part 162, subpart B.

[7] The CFTC's identity theft rules are found in part 162, subpart C (Identity Theft Red Flags) of the CFTC's regulations. 17 CFR part 162, subpart C.

[8] The CFTC understands that CFTC-regulated entities generally do not issue credit or debit cards, but instead may partner with other entities, such as banks, that issue cards on their behalf. These other entities, which are not regulated by the CFTC, are already subject to substantially similar change of address obligations pursuant to other federal regulators' identity theft red flags rules. Therefore, the CFTC does not expect that any CFTC-regulated entities will be subject to the related information collection requirements under the CFTC's identity theft rules.

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

[DFC–008]

Submission for OMB Review; Comments Request

AGENCY: U.S. International Development Finance Corporation (DFC).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the provisions of the Paperwork Reduction Act, agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is modifying an existing approved information collection for OMB review and approval and requests public review and comment on the submission. Comments are being solicited on the need for the information; the accuracy of the burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: Comments must be received by November 28, 2022.

ADDRESSES: Comments and requests for copies of the subject information collection may be sent by any of the following methods:

- *Mail:* Deborah Papadopoulos, Agency Submitting Officer, U.S. International Development Finance Corporation, 1100 New York Avenue NW, Washington, DC 20527.
- *Email: fedreg@dfc.gov.*

Instructions: All submissions received must include the agency name and agency form number or OMB form number for this information collection. Electronic submissions must include the agency form number in the subject line to ensure proper routing. Please note that all written comments received in response to this notice will be considered public records.

FOR FURTHER INFORMATION CONTACT: Agency Submitting Officer: Deborah Papadopoulos, (202) 357–3979.

SUPPLEMENTARY INFORMATION: This notice informs the public that DFC will submit to OMB a request for approval of the following information collection.

Summary Form Under Review

Title of Collection: Development Outcomes Survey (DOS).

Type of Review: Revision of a currently approved information collection.

Agency Form Number: DFC–008.

OMB Form Number: 3015–0015.

Frequency: Once per DFC project per year.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Estimated Number of Annual Number of Respondents: 650.

Estimated Time per Respondent: 2 hours.

Total Estimated Number of Annual Burden Hours: 1,300 hours.

Abstract: The Development Outcomes Survey (DOS) is the principal document used by DFC to review development performance and monitor projects supported by DFC. It is a comprehensive survey that is also used to determine the project's compliance with environmental, labor, and economic policies, as consistent with DFC's authorizing legislation.

Dated: September 26, 2022.

Nichole Skoyles,

Administrative Counsel, Office of the General Counsel.

[FR Doc. 2022–21161 Filed 9–28–22; 8:45 am]

BILLING CODE 3210–02–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: National Nuclear Security Administration, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Atomic Energy between the Government of the United States of America and the Government of Canada, as amended.

DATES: This subsequent arrangement will take effect no sooner than October 14, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Ferkile, Office of Nonproliferation and Arms Control, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–8868 or email: *andrea.ferkile@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns two retransfers from Cameco Corporation in Port Hope, Ontario, Canada, one to Urenco Ltd. in Almelo, the Netherlands, and one to Urenco Deutschland GmbH, in Gronau, Germany, for toll enrichment. Each retransfer will consist of 946,746,000 g of U.S.-obligated natural uranium hexafluoride (UF6), 640,000,000 g of which is natural uranium. Upon transfer to Urenco Ltd. in Almelo, the Netherlands, and Urenco Deutschland GmbH, in Gronau, Germany, the material will become subject to the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy between the United States of America and the European Atomic Energy Community.

Pursuant to the authority in section 131 a. of the Atomic Energy Act of 1954, as delegated, I have determined that this proposed subsequent arrangement concerning the retransfer of U.S.-obligated nuclear material will not be inimical to the common defense and security of the United States of America.

Signing Authority

This document of the Department of Energy was signed on September 23, 2022, by Corey Hinderstein, Deputy Administrator for Defense Nuclear Nonproliferation, 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 September 23, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21039 Filed 9–28–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–32–000]

Commission Information Collection Activities (FERC–551) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection FERC–551 (Reporting of Flow Volume and Capacity by Interstate Natural Gas Pipelines).

DATES: Comments on the collection of information are due November 28, 2022.

ADDRESSES: You may submit your comments (identified by Docket No. IC22–32–000) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) Delivery:* Addressed to: Federal Energy Regulatory Commission, Secretary of the

Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–551, Reporting of Flow Volume and Capacity by Interstate Natural Gas Pipelines.

OMB Control No.: 1902–0243.

Type of Request: Three-year extension of the FERC–551 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission is authorized to facilitate price transparency in markets for the sale or transportation of natural gas in interstate commerce, regarding the public interest, the integrity of those markets, fair competition, and the protection of consumers. FERC–551 uses the information provided by pipelines as part of its overall implementation of the statutory provisions of section 23 of the Natural Gas Act (NGA), 16 U.S.C. 717t–2. More specifically, the Commission relies, in part, on section 23(a)(1) of the NGA, for authority to collect this information and uses the pipelines' FERC–551 postings as part of fulfilling the transparency provisions of section 23(a)(1) of the NGA. The data requirements for pipelines are in listed the Code of Federal Regulations (CFR) under 18 CFR 284.13, reporting requirements for interstate pipelines. The Commission has directed that the data requirements under FERC–551 are to be posted on interstate pipelines' websites and provided in downloadable file formats, in conformity with 18 CFR 284.12.

The posting requirements are based on the Commission's authority under section 23 of the NGA (as added by the Energy Policy Act of 2005), which provides, in relevant part, that the Commission may issue such rules as necessary and appropriate to provide for the dissemination of ''information about the availability and prices of natural gas at wholesale and in interstate commerce.'' [1] This provision enhances the Commission's authority to ensure confidence in the Nation's natural gas markets. The Commission's market-oriented policies for the wholesale natural gas industry require that interested persons have broad confidence that reported market prices accurately reflect the interplay of legitimate market forces. Without confidence in the efficiency of price formation, the true value of transactions is very difficult to determine. Further, price transparency facilitates ensuring that jurisdictional prices are ''just and reasonable.'' [2]

The posting of FERC–551 information occurs on a daily basis. The data must be available for download for not less than 90 days from the date of posting and must be retained by the pipeline for three years.

The daily posting requirements for major non-interstate pipelines prescribed in the Commission's Order No. 720 are no longer required. The number of respondents used to develop the burden estimates do not include any major non-interstate pipelines.

Type of Respondents: Interstate Natural Gas Pipelines.

Estimate of Annual Burden:[3] The Commission estimates the total public reporting burden and cost for this information collection as follows:

FERC–551—Reporting of Flow Volume and Capacity by Interstate Natural Gas Pipelines

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response [4]	Total annual burden hours & total annual cost	Burden hours & cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC–551	181	365	66,065	0.5 hours; $37	33,032.50 hrs.; $2,444,405	182.5 hrs.; $13,505

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) 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.

[1] Section 23(a)(2) of the NGA, 15 U.S.C. 717t–2(a)(2) (2000 & Supp. V 2005).

[2] *See* sections 4 and 5 of the NGA, 15 U.S.C. 717c and 717d.

[3] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[4] The hourly figure (wages plus benefits) is based on the average of the occupational categories for 2022 found on the Bureau of Labor Statistics website (*http://www.bls.gov/oes/current/naics2_22.htm* and *http://www.bls.gov/news.release/ecec.nr0.htm*):

—Management (Occupation Code: 11–0000): $102.41

—Business (Occupation Code: 13–0000): $47.71

—Financial (Occupation Code: 13–2951): $70.68

These various occupational categories' wage (and benefits) figures are averaged and weighted equally, giving an average of $73.60/hour. The resulting wage figure is rounded to $74.00/hour for use in calculating wage figures in the FERC–551 renewal.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21148 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 9821–108]

Ampersand Ogdensburg Hydro LLC; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Application:* Notice of Intent (NOI) to File License Application and Request to Use the Traditional Licensing Process (TLP).

b. *Project No.:* 9821–108.

c. *Date filed:* May 27, 2022.

d. *Submitted by:* Ampersand Ogdensburg Hydro LLC (Ogdensburg Hydro).

e. *Name of Project:* Ogdensburg Hydroelectric Project.

f. *Location:* Located on the Oswegatchie River near the City of Ogdensburg in Saint Lawrence County, New York. The project does not occupy any federal land.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Mr. Sayad Moudachirou, Licensing Manager, Ampersand Ogdensburg Hydro LLC, 717 Atlantic Avenue, Boston, MA 02111. Phone: (617) 933–7206, Email: *sayad@ampersandenergy.com.*

i. *FERC Contact:* Chris Millard, Phone: (202) 502–8256, email: christopher. *millard@ferc.gov.*

j. Ogdensburg Hydro filed its request to use the TLP on May 27, 2022 and provided public notice of its request on August 2, 2022.[1] In a letter dated September 23, 2022, the Director of the Division of Hydropower Licensing approved Ogdensburg Hydro's request to use the TLP.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the New York State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Ogdensburg Hydro as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Ogdensburg Hydro filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD may be viewed on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

o. The applicant states its unequivocal intent to submit an application for a new license for Project No. 9821. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by May 31, 2025.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21149 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

[1] Ogdensburg Hydro's initial notice of its request to use the TLP, published on June 7, 2022, did not correctly state the starting date of the 30-day comment period of the request. The August 2, 2022 notice corrected the starting date error and provided an additional 30-day comment period on the TLP request.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2916–000]

Mesquite Solar 5, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mesquite Solar 5, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 13, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number

field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21143 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2914–000]

Mesquite Solar 4, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mesquite Solar 4, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 13, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21153 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–30–000]

Commission Information Collection Activities (FERC–725N) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection FERC–725N (Mandatory Reliability Standards TPL–007–4, Transmission System Planned Performance for Geomagnetic Disturbance Events).

DATES: Comments on the collection of information are due November 28, 2022.

ADDRESSES: You may submit your comments (identified by Docket No. IC22–30–000) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:
  - *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.
  - *Hand (including courier) delivery:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725N, Mandatory Reliability Standards TPL–007–4, Transmission System Planned Performance for Geomagnetic Disturbance Events.

OMB Control No.: 1902–0264

Type of Request: Extension of the currently approved collection

Abstract: The Reliability Standard TPL–007–4 requires owners and operators of the Bulk-Power System to conduct initial and on-going vulnerability assessments of the potential impact of defined geomagnetic disturbance events on Bulk-Power System equipment and the Bulk-Power System as a whole. Specifically, the Reliability Standard requires entities to develop corrective action plans for vulnerabilities identified through supplemental geomagnetic disturbance vulnerability assessments and requires entities to seek approval from the Electric Reliability Organization of any extensions of time for the completion of corrective action plan items.

On August 8, 2005, Congress enacted into law the Electricity Modernization

Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005).[1] EPAct 2005 added a new section 215 to the FPA, which required a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight, or the Commission can independently enforce Reliability Standards.[2]

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA.[3] Pursuant to Order No. 672, the Commission certified one organization, North American Electric Reliability Corporation (NERC), as the ERO.[4] The Reliability Standards developed by the ERO and approved by the Commission apply to users, owners and operators of the Bulk-Power System as set forth in each Reliability Standard.

On February 7, 2020, the North American Electric Reliability Corporation filed a petition seeking approval of proposed Reliability Standard TPL–007–4 (Transmission System Planned Performance for Geomagnetic Disturbance Events).

NERC's filed petition was noticed on February 11, 2020, with interventions, comments and protests due on or before March 9, 2020. No interventions or comments were received.

The Delegated Letter Order (DLO) was issued on March 19, 2020. The standard went into effect at NERC on October 1, 2020.

Type of Respondents: Generator Owner, Planning Coordinator, Distribution Provider and Transmission Owners.

Estimate of Annual Burden:[5] Our estimates are based on the NERC Compliance Registry Summary of Entities as of September 16, 2022.

The individual burden estimates include the time needed to gather data, run studies, and analyze study results. These are consistent with estimates for similar tasks in other Commission-approved standards. Estimates for the additional average annual burden and cost[6] as follows:

FERC–725N MANDATORY RELIABILITY STANDARDS TPL–007–4, TRANSMISSION SYSTEM PLANNED PERFORMANCE FOR GEOMAGNETIC DISTURBANCE EVENTS

	Annual number[1] of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours & cost ($) per response (4)	Total annual burden hours & cost ($) (rounded) (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
GO[7]	970	1	970	40 hrs.; $3,640	38,800 hrs.; $3,530,800	$3,640
PC[8]	63	1	63	40 hrs.; $3,640	2,520 hrs.; $ 229,320	3,640
DP[9]	310	1	310	40 hrs.; $3,640	12,400 hrs.; $1,128,400	3,640
TO[10]	327	1	327	40 hrs.; $3,640	13,080 hrs.; $1,190,280	3,640
Total			1,670		66,800 hours; $6,078,800.	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) 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.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21150 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR22–67–000.

Applicants: Comanche Trail Pipeline, LLC.

Description: § 284.123(g) Rate Filing: Comanche Trail Pipeline, LLC. Certification of Unchanged State Rates, 10/1/2022 to be effective 10/1/2022.

Filed Date: 9/22/22.

Accession Number: 20220922–5068.

Comment Date: 5 p.m. ET 10/13/22.

§ 284.123(g) Protest: 5 p.m. ET 11/21/22.

Docket Numbers: PR22–68–000.

Applicants: Trans-Pecos Pipeline, LLC.

Description: § 284.123(g) Rate Filing: Trans-Pecos Pipeline, LLC Certification of Unchanged State Rates, 10/1/2022 to be effective 10/1/2022.

Filed Date: 9/22/22.

Accession Number: 20220922–5069.

Comment Date: 5 p.m. ET 10/13/22.

§ 284.123(g) Protest: 5 p.m. ET 11/21/22.

Docket Numbers: RP22–1236–000.

[1] Energy Policy Act of 2005, Public Law 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (codified at 16 U.S.C. 824*o*).

[2] 16 U.S.C. 824*o*(e)(3).

[3] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[4] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *order on compliance,* 118 FERC ¶ 61,190, *order on reh'g,* 119 FERC ¶ 61,046 (2007), *aff'd sub nom. Alcoa Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[5] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[6] Commission staff estimates that the industry's skill set and cost (for wages and benefits) for FERC–725N (1) are approximately the same as the Commission's average cost. The FERC 2022 average salary plus benefits for one FERC full-time equivalent (FTE) is $188,922/year (or $91.00/hour).

[7] Generator Owner.

[8] Planning Coordinator.

[9] Distribution Provider.

[10] Transmission Owner.

Applicants: Midcontinent Express Pipeline LLC.

Description: § 4(d) Rate Filing: Non-Conforming FTS to be effective 11/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5005.

Comment Date: 5 p.m. ET 10/5/22.

Docket Numbers: RP22–1237–000.

Applicants: Guardian Pipeline, L.L.C.

Description: § 4(d) Rate Filing: EPCR Semi-Annual Adjustment—Fall 2022 to be effective 11/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5022.

Comment Date: 5 p.m. ET 10/5/22.

Docket Numbers: RP22–1238–000.

Applicants: Midwestern Gas Transmission Company.

Description: § 4(d) Rate Filing: Annual Load Management Service Cost Reconciliation Adjustment—2022 to be effective 11/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5023.

Comment Date: 5 p.m. ET 10/5/22.

Docket Numbers: RP22–1239–000.

Applicants: Viking Gas Transmission Company.

Description: § 4(d) Rate Filing: Semi-Annual Fuel and Loss Retention Percentage Adjustment—Winter 2022 to be effective 11/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5024.

Comment Date: 5 p.m. ET 10/5/22.

Docket Numbers: RP22–1240–000.

Applicants: Guardian Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Transporters Use Gas Annual Adjustment—Fall 2022 to be effective 11/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5029.

Comment Date: 5 p.m. ET 10/5/22.

Docket Numbers: RP22–1241–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Compliance filing: AGT SEP 2022 OFO Penalty Disbursement Report to be effective N/A.

Filed Date: 9/23/22.

Accession Number: 20220923–5034.

Comment Date: 5 p.m. ET 10/5/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding. The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number. eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21152 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–115–000.

Applicants: MN8 Energy LLC.

Description: Supplement to August 30, 2022, Joint Application for Authorization Under Section 203 of the Federal Power Act of MN8 Energy LLC, et al.

Filed Date: 9/21/22.

Accession Number: 20220921–5099.

Comment Date: 5 p.m. ET 9/28/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL19–58–016.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance Filing Concerning Certain Reserve Pricing Provisions in EL19–58 to be effective 10/1/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5089.

Comment Date: 5 p.m. ET 10/13/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–1857–001.

Applicants: Louisville Gas and Electric Company.

Description: Compliance filing: OMU Settlement Compliance Filing to be effective N/A.

Filed Date: 9/23/22.

Accession Number: 20220923–5010.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2117–002.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2022–09–23_SA 3454 Entergy Arkansas-Flat Fork 2nd Sub 1st Rev GIA (J907 J1434) to be effective 6/2/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5028.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2388–001.

Applicants: Mississippi Power Company.

Description: Compliance filing: MRA 30 Compliance Filing to be effective 9/14/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5050.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2510–001.

Applicants: The Narragansett Electric Company.

Description: Tariff Amendment: Narragnsett MBR Tariff Revisions to be effective 5/25/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5031.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2609–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2022–09–23_SA 3413 Ameren IL-Cass County Solar Project Sub 2nd Rev GIA (J859) to be effective 7/22/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5025.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2827–001.

Applicants: Bluegrass Solar, LLC.

Description: Tariff Amendment: Amendment to 1 to be effective 9/23/2022.

Filed Date: 9/22/22.

Accession Number: 20220922–5152.

Comment Date: 5 p.m. ET 10/3/22.

Docket Numbers: ER22–2921–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: First Revised ISA, Service Agreement No. 5220; Queue No. AD1–148 to be effective 8/24/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5008.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2922–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Silver State South Solar Project ED&P LA TOT381–TOT405 (SA290) to be effective 9/24/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5048.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2923–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: UAMPS Const Agmt Santa Clara BTM Resource Modeling to be effective 11/23/2022.

Filed Date: 9/23/22.

Accession Number: 20220923–5074.

Comment Date: 5 p.m. ET 10/14/22.

Docket Numbers: ER22–2924–000.
Applicants: RWE Supply & Trading Americas, LLC.
Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 11/1/2022.
Filed Date: 9/23/22.
Accession Number: 20220923–5079.
Comment Date: 5 p.m. ET 10/14/22.
Docket Numbers: ER22–2925–000.
Applicants: Jicarilla Solar 1 LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 11/15/2022.
Filed Date: 9/23/22.
Accession Number: 20220923–5121.
Comment Date: 5 p.m. ET 10/14/22.
Docket Numbers: ER22–2926–000.
Applicants: Jicarilla Storage 1 LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 12/1/2022.
Filed Date: 9/23/22.
Accession Number: 20220923–5122.
Comment Date: 5 p.m. ET 10/14/22.
Docket Numbers: ER22–2927–000.
Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Mid-Atlantic Interstate Transmission, LLC submits tariff filing per 35.13(a)(2)(iii: MAIT submits One ECSA, SA No. 6492 Klecknersville to be effective 11/23/2022.
Filed Date: 9/23/22.
Accession Number: 20220923–5141.
Comment Date: 5 p.m. ET 10/14/22.
Docket Numbers: ER22–2928–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: SPP–AECI JOA Revisions to Add Provisions for Emergency Energy Assistance to be effective 9/24/2022.
Filed Date: 9/23/22.
Accession Number: 20220923–5151.
Comment Date: 5 p.m. ET 10/14/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21146 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–510–000]

Gulf South Pipeline Company, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on September 16, 2022, Gulf South Pipeline Company, LLC (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, TX 77046, filed an application under section 7(c) of the Natural Gas Act (NGA), and Part 157 and 284 of the Commission's regulations requesting authorization to modify the working gas and base gas capacities at its Bistineau Gas Storage Facility (Bistineau Storage) located in Bienville and Bossier Parishes, Louisiana.[1]

Gulf South proposes to reduce the level of its interruptible working gas capacity and increase its level of its base gas capacity based on the results of a third-party engineering study. Gulf South seeks authorization to (i) reclassify 13.54 billion cubic feet (Bcf) of working gas capacity currently utilized for interruptible storage services (ISS) as base gas capacity to establish a new base gas capacity of 62.30 Bcf, and (ii) reclassify for use as base gas 13.54 Bcf of excess operational gas owned by Gulf South (Reclassification Project or Project). Gulf South also requests Commission approval of the accounting entries included as Exhibit Z–1 which reflect the reclassification of this gas.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding the proposed project should be directed to J. Kyle Stephens, Vice President of Regulatory Affairs or to Juan Eligio Jr., Manager of Regulatory Affairs, Gulf South Pipeline Company, LLC, 9 Greenway Plaza, Houston, Texas 77046 or by phone at (713) 479–8033, or by email at *kyle.stephens@bwpipelines.com* or phone at (713) 479–3480 or by email at *juan.eligio@bwpipelines.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are two ways to become involved in the Commission's review of this project: you can file comments on the project, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on October 14, 2022.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly

[1] Gulf South is not seeking abandonment authorization in this application as Gulf South's proposal seeks only to reclassify the capacity at Bistineau with no changes to firm services.

[2] 18 CFR (Code of Federal Regulations) 157.9.

recorded, please submit your comments on or before October 14, 2022.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number CP22–510–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address below. Your written comments must reference the Project docket number (CP22–510–000).

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[3] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is October 14, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as the your interest in the proceeding. [For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene.] For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP22–510–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below . Your motion to intervene must reference the Project docket number CP22–510–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Motions to intervene must be served on the applicant either by mail or email at: 9 Greenway Plaza, Suite 2800, Houston, Texas 77046 or at *kyle.stephens@bwpipelines.com* and *juan.eligio@bwpipelines.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [6] motions to intervene are automatically granted by operation of Rule 214(c)(1).[7] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[8] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with

[3] 18 CFR 385.102(d).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

[6] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[7] 18 CFR 385.214(c)(1).

[8] 18 CFR 385.214(b)(3) and (d).

notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on October 14, 2022.

Dated: September 23, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–21151 Filed 9–28–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0047; FRL–10259–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Greenhouse Gas Emissions for New Electric Utility Generating Units (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NSPS for Greenhouse Gas Emissions for New Electric Utility Generating Units (EPA ICR Number 2465.05, OMB Control Number 2060–0685), 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 November 30, 2022. Public comments were previously requested, via the **Federal Register,** on April 8, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0047, to: (1) EPA online using *https://www.regulations.gov/* (our preferred method), or by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. The 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: 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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, 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 New Source Performance Standards (NSPS) for Greenhouse Gas Emissions for New Electric Utility Generating Units were proposed on June 2, 2014 and promulgated on October 23, 2015. Amendments to 40 CFR part 60, subpart TTTT were proposed on December 6, 2018, but EPA did not finalize amendments to the 2015 final rule. On January 13, 2021, EPA finalized a pollutant-specific significant contribution finding for this source category, which was later vacated and remanded on April 5, 2021. These regulations apply to either newly constructed, modified or reconstructed facilities with electric utility generating units (EGUs), including any steam generating unit, IGCC, or stationary combustion turbine that commenced construction after January 8, 2014 or commenced reconstruction after June 18, 2014. To be considered an EGU the unit must be: (1) capable of combusting more than 250 MMBtu/h heat input of fossil fuel; and (2) serve a generator capable of supplying more than 25 MW net to a utility distribution system (*i.e.,* for sale to the grid). New facilities include those that commenced construction, modification or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 60, subpart TTTT. In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NSPS.

Form Numbers: None.

Respondents/affected entities: Electric utility generating units.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart TTTT).

Estimated number of respondents: 92 (total).

Frequency of response: Initially, quarterly.

Total estimated burden: 3,130 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $376,000 (per year), which includes no annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The increase in burden from the most recently approved ICR is due to an adjustment(s). The adjustment increase in burden from the most-recently approved ICR is due to an increase in the number of respondents. Based on our consultation with the Agency's internal industry experts and review of data from EPA's Clean Air Markets Division and the U.S. Energy Information Administration, the electric utility sector is undergoing significant changes and the number of respondents and new sources expected over the next three years has increased significantly from the most recently approved ICR.

Although we are assuming there will be 16 new sources per year subject to 40 CFR part 60, subpart TTTT, there is no change in the capital/startup vs. operation and maintenance (O&M) costs as discussed in section 6(b)(iii) compared with the costs in the most-recently approved ICR. There are no capital/startup and/or O&M costs for this ICR. As described in a previous **Federal Register** notice (84 FR 25046), this NSPS imposes a minimal information collection burden on affected sources beyond what sources would already be subject to under the authorities of CAA Parts 75 (Acid Rain Program CEM requirements) and 98

(Mandatory GHG Reporting, applicable to EGUs that capture CO2). OMB has previously approved the information collection requirements contained in the existing Part 75 and 98 regulations (40 CFR part 75 and 40 CFR part 98) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* and has assigned OMB control numbers 2060–0626 and 2060–0629, respectively. Apart from certain reporting costs to comply with the emission standards under the rule, there are no additional information collection costs, as the information required by the rule is already collected and reported by other regulatory programs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21175 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0073; FRL–10260–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request, Distribution of Offsite Consequence Analysis Information Under the Clean Air Act (CAA), as Amended

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), ''Distribution of Offsite Consequence Analysis Information under Section 112(r)(7)(H) of the Clean Air Act (CAA), as amended,'' (EPA ICR No. 1981.08, OMB Control No. 2050–0172) 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 November 30, 2022. Public comments were previously requested via the **Federal Register** on March 1, 2022 (87 FR 11425). EPA received no comments during the 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Comments must be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2003–0073, to (1) EPA online using *www.regulations.gov* (our preferred method), or by mail to EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA. 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.

FOR FURTHER INFORMATION CONTACT: Wendy Hoffman, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8794; email address: *hoffman.wendy@epa.gov.*

SUPPLEMENTARY INFORMATION: 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: Pursuant to section 3506(c)(2)(A) of the PRA, in the first FR notice (87 FR 11425) published on March 1, 2022, EPA solicited comments and information pertaining to the distribution of offsite consequence analysis information under the accidental release prevention requirements; Risk Management Programs under the Clean Air Act Section 112(r)(7). The regulations include requirements for submittal of a Risk Management Plan (RMP) to EPA, which includes information on offsite consequence analysis (OCA) as well as other elements of the Risk Management Program.

The Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRA), published on August 4, 2000 (65 FR 48108), required the President, who delegated to EPA and the Department of Justice (DOJ), the responsibility to promulgate regulations on the distribution of OCA information, imposed minimal information and recordkeeping requirements.

In accordance with the final rule, the Federal Government established 55 reading rooms at Federal facilities geographically distributed across the United States and its territories, where the public may read, but not mechanically copy or remove, paper copies of OCA information for up to 10 stationary sources per calendar month. The public may also obtain OCA information that the Local Emergency Planning Committee (LEPC) in whose jurisdiction the requestor lives or works, is authorized to provide.

The final rule also authorizes and encourages State and local government officials to access OCA information for their official use, and to provide the public with read-only access to OCA sections of RMPs for sources located within the jurisdiction of the LEPC where the person lives or works and for any other stationary sources with vulnerability zones extending into the LEPC's jurisdiction.

EPA also established a Vulnerable Zone Indicator System (VZIS) which informs any person located in any state whether an address specified by that person might be within the vulnerable zone of one or more stationary sources, according to the data reported in RMPs. The VZIS is available on the internet. Members of the public who do not have access to the internet are able to obtain the same information by regular mail request to the EPA. 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 EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Form Numbers: None.

Respondents/affected entities: State and local agencies and the public.

Respondent's obligation to respond: Required to obtain or retain a benefit (40 CFR 1400).

The annual respondent universe for this ICR is 315 state and local agencies, LEPCs and individuals (public). The total includes 15 State agencies and three LEPCs that send EPA letters of request for OCA data, five states that experience reading room visits, and three LEPCs that hold five public meetings each year. The public component of the total includes 15 individuals who visit Federal and State reading rooms each year and 262 individuals who request VZIS data. The three LEPCs that hold public meetings are assumed to be the same three LEPCs that send letters of request for OCA data.

All other respondents are assumed to be unique.

Estimated number of respondents: 15 (total).

Frequency of response: As necessary.

Total estimated burden: 663 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $29,800 (per year), includes $81 annual operation & maintenance costs.

Changes in the estimates: EPA estimates a slight increase in the burden to respondents for this renewal compared to the previous ICR renewal. Even though reading room visits were greatly reduced, if not stopped altogether because of COVID 19 restrictions during the previous ICR period and reading room visits had been declining prior to the COVID restrictions because of the increased use of the website *www.rtk.net.*

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21185 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0046; FRL–10258–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Group I Polymers and Resins (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Group I Polymers and Resins (EPA ICR Number 2410.05, OMB Control Number 2060–0665), 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 November 30, 2022. Public comments were previously requested, via the **Federal Register**, on April 8, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0046, EPA online using *https://www.regulations.gov/* (our preferred method), or by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. The 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: 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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Group I Polymers and Resins (40 CFR part 63, subpart U) were proposed on June 12, 1995; promulgated on September 5, 1995, and amended on: June 19, 2000; July 16, 2001; December 16, 2008; and April 21, 2011. These regulations apply to existing and new elastomer product process units (EPPU) and associated equipment, including waste management units, maintenance wastewater, heat exchange systems, and equipment required either by or utilized to comply with this Subpart located at facilities that are major sources of hazardous air pollutants (HAPs) and are classified in the Group I Polymers and Resins source category. The Group I Polymers and Resins source category includes the following categories: Butyl Rubber Production, Epichlorohydrin Elastomers Production, Ethylene Propylene Rubber Production, Hypalon Production, Neoprene Production, Nitrile Butadiene Rubber (NBR) Production, Polybutadiene Rubber Production, Polysulfide Rubber Production, and Styrene Butadiene Rubber and Latex Production. New facilities include those that either commenced construction, or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart U.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Facilities with elastomer product process units (EPPU) and associated equipment.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart U).

Estimated number of respondents: 19 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 56,400 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $12,000,000 (per year), which includes $5,230,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an insignificant increase in burden from the most recently approved ICR due to an adjustment. This increase (not reflected in the rounded total) is not due to any program changes. The adjustment increase is due to a correction of the calculation used to summarized the burden estimates for individual reporting requirements.

Since there are no changes in the regulatory requirements and there is no significant industry growth, there are no

changes in the capital/startup and/or operation and maintenance (O&M) costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21122 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–SFUND–2015–0100; FRL–10265–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Continuous Release Reporting Requirement Including Analysis for Use of Continuous Release Reporting Form (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Continuous Release Reporting Requirement Including Analysis for Use of Continuous Release Reporting Forms (EPA ICR Number 1445.15, OMB Control Number 2050–0086) 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 November 30, 2022. Public comments were previously requested via the **Federal Register** on February 24, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–SFUND–2015–0100, online using *www.regulations.gov* (our preferred method), or by mail to EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

The 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: Wendy Hoffman, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8794; email address: *hoffman.wendy@epa.gov.*

SUPPLEMENTARY INFORMATION: 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: Pursuant to section 3506(c)(2)(A) of the PRA, in the first FR notice (87 FR 10361 published on February 24, 2022, EPA solicited comments and information pertaining to the Continuous Release Reporting Requirements (CRRR) under Section 103(a) of CERCLA, as amended. CRRR requires the person in charge of a vessel or facility immediately to notify the National Response Center (NRC) of a hazardous substance release into the environment if the amount of the release equals or exceeds the substance's reportable quantity (RQ) (found in Table 302.4 of 40 CFR 302.4). If the source and chemical composition of the continuous release do not change and the level of the continuous release does not significantly increase, a follow-up written report to EPA Headquarters one year after submission of the initial written report is also required. The person in charge must notify the NRC and EPA Region of a change in the source or composition of the release, and under section 103(a) of CERCLA, a significant increase must be reported immediately to the NRC. Finally, any change in information submitted in support of a continuous release notification must be reported to EPA Headquarters. Section 103(f)(2) of CERCLA provides facilities relief from per-occurrence notification release requirements if the subject release is continuous and stable in quantity and rate.

CRRR allows the Federal government to determine whether a Federal response action is required to control or mitigate any potential adverse effects to public health, welfare or the environment. The release information is also available to EPA program offices and other Federal agencies who evaluate the potential need for additional regulations, new permitting requirements for specific substances or sources, or improved emergency response planning. State and local government authorities and facilities subject to the CRRR use the release information for local emergency response planning. The public, which has access to release information through the Freedom of Information Act, may request release information on what types of releases are occurring in different localities and what actions, if any, are being taken to protect public health, welfare and the environment.

Form Numbers: EPA Form 6100–10, Continuous Release Reporting Form.

Respondents/affected entities: Entities potentially affected by this action are not defined. The use and release of hazardous substances are pervasive throughout industry. EPA expects many different industrial categories to report hazardous substance releases under the provisions of the CRRR. No one industry sector or group of sectors is disproportionately affected by the information collection burden.

Respondent's obligation to respond: Mandatory if respondents want reduced reporting for continuous releases.

Estimated number of respondents: 4,250, including 25 State and local government agencies.

Frequency of response: On occasion.

Total estimated burden: 38,625 hours (average per year, including 75 hours for State and local government agencies). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $2,487,450 (average per year), including $8,200 annualized capital or operation & maintenance costs (average per year) and $4,178 in State and local government agency costs (average per year).

Changes in Estimates: Compared to the previous ICR renewal, the estimated respondent unit burden per CRRR submission has remained the same and the estimated annual total respondent burden has decreased by 88 percent,

from an estimated 334,472 average annual hours in the previous ICR renewal to an estimated 38,625 average annual hours in this renewal. This ICR renewal was updated to reflect the review of available information gathered while moving the program submissions from EPA Regions to a central location at EPA HQ. The previous ICRs had overestimated the burden on both industry and governments. The typical facility does not make an average of eight separate submissions, as previously estimated, but rather, one. While the burden to generate a CRRR submission remains the same, the overall submissions and number of chemicals reported are reduced. This reduces the labor burden for both industry and governments.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21169 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0039; FRL–10256–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Area Sources: Primary Copper Smelting, Secondary Copper Smelting, and Primary Nonferrous Metals-Zinc, Cadmium, and Beryllium (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Area Sources: Primary Copper Smelting, Secondary Copper Smelting, and Primary Nonferrous Metals-Zinc, Cadmium, and Beryllium (EPA ICR Number 2240.08, OMB Control Number 2060–0596), 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 November 30, 2022. Public comments were previously requested via the **Federal Register** on April 8, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0039, online using *https://www.regulations.gov/* (our preferred method), by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. The 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: 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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Area Sources: Primary Copper Smelting, Secondary Copper Smelting, and Primary Nonferrous Metals-Zinc, Cadmium, and Beryllium (40 CFR part 63, subparts EEEEEE, FFFFFF, and GGGGGG), apply to both new and existing primary copper smelting facilities (Subpart EEEEEE), new secondary copper smelting facilities (Subpart FFFFFF), and both new and existing primary zinc or beryllium production facilities (Subpart GGGGGG) that are an area source of hazardous air pollutant (HAP) emissions. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to the NESHAP.

Form Numbers: None.

Respondents/affected entities: Owners and operators of new and existing primary copper smelting facilities, new secondary copper smelting facilities, and new and existing primary zinc or beryllium production facilities that are area sources of HAP.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subparts EEEEEE, FFFFFF, and GGGGGG).

Estimated number of respondents: 3 (total).

Frequency of response: Initially.

Total estimated burden: 41 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $4,970 (per year), includes no annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The decrease in burden from the most-recently approved ICR is due to an adjustment(s). The adjustment decrease in burden from the most recently approved ICR is due to an updated respondent count that showed fewer primary copper sources than were estimated in the most-recently approved ICR. This count is based on data collected during a recently proposed rulemaking for primary copper smelting area sources (87 FR 1616; January 11, 2022). and better reflects the current industry. Because the proposed rulemaking is not yet finalized, this ICR renewal reflects the burden of the recordkeeping and reporting requirements of the existing regulation. There are no capital/startup vs. operation and maintenance (O&M) costs for the affected sources.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21121 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0042; FRL–10257–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Area Sources: Asphalt Processing and Asphalt Roofing Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Asphalt Processing and Asphalt Roofing Manufacturing (EPA ICR Number 2352.06, OMB Control Number 2060–0634), 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 November 30, 2022. Public comments were previously requested, via the **Federal Register**, on April 8, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 31, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0042, online using *https://www.regulations.gov/* (our preferred method), or by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. The 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: 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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Area Sources: Asphalt Processing and Asphalt Roofing Manufacturing (40 CFR part 63, subpart AAAAAAA) were proposed on July 9, 2009, promulgated on December 2, 2009, and amended on March 18, 2010. These regulations apply to existing facilities and new facilities that are Area Sources and that either process asphalt or manufacture asphalt roofing products. New facilities include those that commenced either construction, modification or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart AAAAAAA.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to the NESHAP.

Form Numbers: None.

Respondents/affected entities: Existing and new facilities that are area sources and that process asphalt or manufacture asphalt roofing products.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart AAAAAAA).

Estimated number of respondents: 59 (total).

Frequency of response: Semiannually.

Total estimated burden: 2,370 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $286,000 (per year), which includes $885 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The increase in burden from the most recently approved ICR is due to an adjustment. The adjustment increase is due to an increase in the number of respondents based on review of the results of a Section 114 request from 2017, EPA's ECHO database, and facility permits. There is an increase in the operation and maintenance (O&M) costs due to the increased number of respondents.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–21120 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0289; FR ID 106784]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to

further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before November 28, 2022. 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, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0289.

Title: Section 76.601, Performance Tests; Section 76.1704, Proof of Performance Test Data; Section 76.1717, Compliance with Technical Standards.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, and state, local, or tribal government.

Number of Respondents: 4,085 respondents, 6,433 responses.

Estimated Time per Response: 0.5 to 70 hours.

Frequency of Response: Recordkeeping requirement, Semi-annual and Triennial reporting requirements; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 4(i) and 624(e) of the Communications Act of 1934, as amended.

Total Annual Burden: 166,405 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The information collection requirements contained in 47 CFR 76.1705 requires that the operator of each cable television system shall maintain at its local office a current listing of the cable television channels which that system delivers to its subscribers. 47 CFR 76.601(b) and (c) require cable systems with over 1,000 subscribers that deliver analog signals to conduct semi-annual proof of performance tests and triennial proof of performance tests for color testing. 47 CFR 76.601 also states that prior to additional testing pursuant to section 76.601(c), the local franchising authority shall notify the cable operator, who will then be allowed thirty days to come into compliance with any perceived signal quality problems which need to be corrected. 47 CFR 76.1704 requires that proof of performance test required by 47 CFR 76.601 shall be maintained on file at the operator's local business office for at least five years. The test data shall be made available for inspection by the Commission or the local franchiser, upon request. If a signal leakage log is being used to meet proof of performance test recordkeeping requirement in accordance with section 76.601, such a log must be retained for the period specified in 47 CFR 76.601(d). 47 CFR 76.1705 requires that the operator of each cable television system shall maintain at its local office a current listing of the cable television channels which that system delivers to its subscribers. 47 CFR 76.1717 states that an operator shall be prepared to show, on request by an authorized representative of the Commission or the local franchising authority, that the system does, in fact, comply with the technical standards rules in part 76, subpart K.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–21147 Filed 9–28–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8082–N]

RIN 0938–AU48

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2023

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

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2023. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2023, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts.

DATES: The premium and related amounts announced in this notice are effective January 1, 2023.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION: The monthly actuarial rates for 2023 are $323.70 for aged enrollees and $357.90 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2023 is $164.90, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus the $3.00 repayment amount required under current law. (The 2022 standard premium rate was $170.10, which included the $3.00 repayment amount.) The Part B deductible for 2023 is $226.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment amount, that individual will have to pay a total monthly premium of about 35, 50, 65, 80, or 85 percent of the total cost of Part B coverage plus a repayment amount of $4.20, $6.00, $7.80, $9.60, or $10.20, respectively. Beginning in 2023, certain Medicare enrollees who are 36 months post kidney transplant, and therefore are no longer eligible for full Medicare coverage, can elect to continue Part B coverage of immunosuppressive drugs by paying a premium. For 2023, the immunosuppressive drug premium is $97.10.

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part of the costs for physicians' services; outpatient hospital services; certain home health services; services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities; and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens and to non-citizens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as

described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible, income-related monthly adjustment amounts, and the immunosuppressive drug premium are included because their determinations are directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

The Part B deductible to be paid by enrollees is also announced. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110.00, section 629 of the MMA (amending section 1833(b) of the Act) required that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2023 Part B deductible is calculated by multiplying the 2022 deductible by the ratio of the 2023 aged actuarial rate to the 2022 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.00.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that the two groups pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal-year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II Social Security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered ''post-institutional'' are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were one-sixth for 1998, one-third for 1999, one-half for 2000, two-thirds for 2001, and five-sixths for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that one-seventh of the cost be transferred in 1998, two-sevenths in 1999, three-sevenths in 2000, four-sevenths in 2001, five-sevenths in 2002, and six-sevenths in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the MMA, which amended section 1839 of the Act, requires that, starting on January 1, 2007, the Part B premium a beneficiary pays each month be based on that individual's annual income. (The MMA specified that there be a 5-year transition period to reach full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period, which ended in 2009.) Specifically, if a beneficiary's modified adjusted gross income is greater than the legislated threshold amounts (for 2023, $97,000 for a beneficiary filing an individual income tax return and $194,000 for a beneficiary filing a joint tax return), the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25-percent premium, these beneficiaries now have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary can now be responsible for 35, 50, 65, 80, or 85 percent of the estimated total cost of Part B coverage, rather than 25 percent.

Section 402 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) modified the income thresholds beginning in 2018, and section 53114 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) further modified the income thresholds beginning in 2019. For years beginning in 2019, the BBA of 2018 established a new income threshold. If a beneficiary's modified adjusted gross income is greater than or equal to $500,000 for a beneficiary filing an individual income tax return and $750,000 for a beneficiary filing a joint tax return, the beneficiary is responsible for 85 percent of the estimated total cost of Part B coverage. The BBA of 2018 specified that these new income threshold levels be inflation-adjusted beginning in 2028. The end result of the higher premium is that the Part B premium subsidy is reduced, and less general revenue financing is required, for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy continues to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but it will be reduced for beneficiaries with income above these thresholds.

The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) established a new basis for Medicare Part B eligibility for post-kidney-transplant immunosuppressive drug coverage only. Medicare eligibility due solely to end-stage renal disease generally ends 36 months after a successful kidney transplant. Beginning in 2023, post-kidney-transplant individuals without certain types of insurance coverage can elect to remain enrolled in Part B and receive coverage of immunosuppressive drugs only. The premium for this continuation of coverage is 15 percent of a different aged actuarial rate, which is equal to 100 percent of costs for aged enrollees (rather than the standard aged actuarial rate, which is equal to one-half of the costs for aged enrollees). Enrollees paying the immunosuppressive premium are not subject to the late enrollment penalty and the $3.00 repayment amounts, but they are subject to the hold-harmless provision (described later) and the income-related monthly adjustment amounts. The law requires transfers equal to the reduction in aggregate premiums payable that results from enrollees with coverage only for immunosuppressive drugs paying the immunosuppressive drug Part B premium rather than the standard Part B premium. These transfers are to be treated as premiums payable for general revenue matching purposes.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the State Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2015, the expenditure was made from the trust fund because the allocation was temporarily extended. However, because the extension occurred after the financing was determined, the allocation was not included in the calculation of the financing rates for these years. Section 211 of MACRA permanently extended this expenditure, which is included in the calculation of the Part B actuarial rates for 2016 and subsequent years.

Another provision affecting the calculation of the Part B premium is section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100–360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234) did not repeal the revisions to section 1839(f) of the Act made by MCCA 88.) Section 1839(f) of the Act, referred to as the ''hold-harmless'' provision, provides that, if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premium deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual's net monthly payment. This decrease in payment occurs if the increase in the individual's Social Security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to benefits under section 202 or 223 of the Act for November and December of a particular year and the individual's Part B premiums for December and the following January are deducted from the respective month's section 202 or 223 benefits. The hold-harmless provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but December's Part B premium has been deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, the reduced premium for the individual for that January and for each of the succeeding 11 months is the greater of either—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November's monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that apply to the individual's monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

Section 1839 of the Act, as amended by section 601(a) of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), specified that the 2016 actuarial rate for enrollees age 65 and older be determined as if the hold-harmless provision did not apply. The premium revenue that was lost by using the resulting lower premium (excluding the forgone income-related premium revenue) was replaced by a transfer of general revenue from the Treasury, which will be repaid over time to the general fund.

Similarly, section 1839 of the Act, as amended by section 2401 of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116–159), specified that the 2021 actuarial rate for enrollees age 65 and older be determined as the sum of the 2020

actuarial rate for enrollees age 65 and older and one-fourth of the difference between the 2020 actuarial rate and the preliminary 2021 actuarial rate (as determined by the Secretary) for such enrollees. The premium revenue lost by using the resulting lower premium (excluding the forgone income-related premium revenue) was replaced by a transfer of general revenue from the Treasury, which will be repaid over time.

Starting in 2016, in order to repay the balance due (which includes the transfer amounts and the forgone income-related premium revenue from the Bipartisan Budget Act of 2015 and the Continuing Appropriations Act, 2021 and Other Extensions Act), the Part B premium otherwise determined will be increased by $3.00. These repayment amounts will be added to the Part B premium otherwise determined each year and will be paid back to the general fund of the Treasury, and they will continue until the balance due is paid back.

High-income enrollees pay the $3.00 repayment amount plus an additional $1.20, $3.00, $4.80, $6.60, or $7.20 in repayment as part of the income-related monthly adjustment amount (IRMAA) premium dollars, which reduce (dollar for dollar) the amount of general revenue received by Part B from the general fund of the Treasury. Because of this general revenue offset, the repayment IRMAA premium dollars are not included in the direct repayments made to the general fund of the Treasury from Part B in order to avoid a double repayment. (Only the $3.00 monthly repayment amounts are included in the direct repayments.)

These repayment amounts will continue until the balance due is zero. (In the final year of the repayment, the additional amounts may be modified to avoid an overpayment.) The repayment amounts (excluding those for high-income enrollees) are subject to the hold-harmless provision. The original balance due was $9,066,409,000, consisting of $1,625,761,000 in forgone income-related premium revenue plus a transfer amount of $7,440,648,000 from the provisions of the Bipartisan Budget Act of 2015. The increase in the balance due in 2021 was $8,799,829,000, consisting of $946,046,000 in forgone income-related premium income plus a transfer amount of $7,853,783,000 from the provisions of the Continuing Appropriations Act, 2021 and Other Extensions Act. An estimated $10,948,663,000 will have been collected for repayment to the general fund by the end of 2022.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible

The Medicare Part B monthly actuarial rates applicable for 2023 are $323.70 for enrollees age 65 and over and $357.90 for disabled enrollees under age 65. In section II.B. of this notice, we present the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for all enrollees for 2023 is $164.90. The Part B immunosuppressive drug premium is $97.10.

The following are the 2023 Part B monthly premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns.

FULL PART B COVERAGE

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$164.90
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	65.90	230.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	164.80	329.70
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	263.70	428.60
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	362.60	527.50
Greater than or equal to $500,000	Greater than or equal to $750,000	395.60	560.50

For beneficiaries with immunosuppressive drug only Part B coverage, who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns, the 2023 Part B monthly premium rates are as follows:

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$97.10
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	64.70	161.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	161.80	258.90
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	258.90	356.00
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	356.00	453.10
Greater than or equal to $500,000	Greater than or equal to $750,000	388.40	485.50

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

FULL PART B COVERAGE

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$164.90
Greater than $97,000 and less than $403,000	362.60	527.50
Greater than or equal to $403,000	395.60	560.50

The monthly premium rates to be paid by (or on behalf of) beneficiaries with immunosuppressive drug only Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$97.10
Greater than $97,000 and less than $403,000	356.00	453.10
Greater than or equal to $403,000	388.40	485.50

The Part B annual deductible for 2023 is $226.00 for all beneficiaries.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2023

The actuarial assumptions and bases used to determine the monthly actuarial rates and the monthly premium rates for Part B are established by the Centers for Medicare & Medicaid Services' Office of the Actuary. The estimates underlying these determinations are prepared by actuaries meeting the qualification standards and following the actuarial standards of practice established by the Actuarial Standards Board.

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under section 1839 of the Act, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

Because the premium rates are established prospectively, they are subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Trust fund assets must therefore be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine what level of assets is appropriate to cover variation between actual and projected costs. For 2023, the four most important of these factors are (1) the impact of the COVID–19 pandemic on program spending; (2) the difference from prior years between the actual performance of the program and estimates made at the time financing was established; (3) the likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year; and (4) the expected relationship between incurred and cash expenditures. The impact of the pandemic on program spending brings a higher-than-usual degree of uncertainty to projected costs for the 2023 Part B financing. The other three factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2021 and 2022.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets (in millions)	Liabilities [1] (in millions)	Assets less liabilities [1] (in millions)
December 31, 2021	$163,333	$32,618	$130,716
December 31, 2022	192,097	35,045	157,052

[1] These amounts include only items incurred but not paid. They do not include the amounts that are to be paid back to the general fund of the Treasury over time as specified by section 1839 of the Act as amended by section 601(a) of the Bipartisan Budget Act of 2015 and further amended by section 2401 of the Continuing Appropriations Act, 2021 and Other Extensions Act, nor do they include the Accelerated and Advance Payments Program amounts that are to be repaid by providers and returned to the general fund of the Treasury.

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for (1) the projected cost of benefits and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

The monthly actuarial rate for enrollees age 65 and older for 2023 is determined by first establishing per enrollee costs by type of service from program data through 2021 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2020 through December 31, 2023 are shown in Table 2.

As indicated in Table 3, the projected per enrollee amount required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2023 is $332.59. Based on current estimates, the assets at the end of 2022 are sufficient to cover the amount of incurred, but unpaid, expenses, to provide for substantial variation between actual and projected costs, and to accommodate the unusually high degree of uncertainty regarding program costs due to the COVID–19 pandemic. Thus, a negative contingency margin can be included to decrease assets to a more appropriate level. The monthly actuarial rate of $323.70 provides an adjustment of −$5.96 for a contingency margin and −$2.93 for interest earnings.

The contingency margin for 2023 is affected by several factors. In order to take into account the uncertainty and potential impact of the COVID–19 pandemic, assumptions were developed for testing and treatment for COVID–19, utilization of non-COVID-related care, potential costs for COVID–19 vaccines, and possible paths of the pandemic. The Part B projected program costs were developed based on these assumptions and were included in the margin development.

In addition, starting in 2011, manufacturers and importers of brand-name prescription drugs pay a fee that is allocated to the Part B account of the SMI trust fund. For 2023, the total of these brand-name drug fees is estimated to be $2.8 billion. The contingency margin for 2023 has been reduced to account for this additional revenue.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should represent between 15 and 20 percent of the following year's total incurred expenditures. To accomplish this goal, a 17-percent reserve ratio, which is a fully adequate contingency reserve level, has been the normal target used to calculate the Part B premium. At the end of 2022, the reserve ratio is expected to be well above 20 percent. The financing rates for 2023 are set to use excess reserves to reduce the 2023 premium and to move the reserve ratio towards the normal target range. The actuarial rate of $323.70 per month for aged beneficiaries, as announced in this notice for 2023, reflects the combined effect of the factors and legislation previously described and the projected assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD) are prepared in a manner parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the different nature of services offered by the program.

As shown in Table 4, the projected per enrollee amount required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2023 is $410.24. The monthly actuarial rate of $357.90 also provides an adjustment of −$3.59 for interest earnings and −$48.75 for a contingency margin, reflecting the same factors and legislation described previously for the aged actuarial rate at magnitudes applicable to the disabled rate determination. Based on current estimates, the assets associated with the disabled Medicare beneficiaries at the end of 2022 are sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs.

The actuarial rate of $357.90 per month for disabled beneficiaries, as announced in this notice for 2023, reflects the combined net effect of the factors and legislation described previously for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to test the adequacy of the rates using alternative cost growth rate assumptions, the results of which are shown in Table 5. One set represents increases that are higher and, therefore, more pessimistic than the current estimate, and the other set represents increases that are lower and, therefore, more optimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of the historical variation in the respective increase factors. The historical variation may not be representative of the current level of uncertainty due to the COVID–19 pandemic.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of $144,015 million by the end of December 2023 under the cost growth rate assumptions shown in Table 2 and under the assumption that the provisions of current law are fully implemented. This result amounts to 26.3 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of $88,664 million by the end of December 2023 under current law, which amounts to 14.5 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of $230,559 million by the end of December 2023, or 47.6 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that, in a typical year, the premium and general revenue financing established for 2023, together with existing Part B account assets, would be adequate to cover estimated Part B costs for 2023 under current law, should actual costs prove to be somewhat greater than expected. However, the current level of uncertainty due to the pandemic may differ from the historical variation included in this analysis.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, the following are the 2023 Part B monthly premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who file either individual tax returns (and are single individuals, heads of

households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns.

FULL PART B COVERAGE

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$164.90
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	65.90	230.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	164.80	329.70
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	263.70	428.60
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	362.60	527.50
Greater than or equal to $500,000	Greater than or equal to $750,000	395.60	560.50

For beneficiaries with immunosuppressive drug only Part B coverage who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns, the 2023 Part B monthly premium rates are shown below.

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$97.10
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	64.70	161.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	161.80	258.90
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	258.90	356.00
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	356.00	453.10
Greater than or equal to $500,000	Greater than or equal to $750,000	388.40	485.50

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

FULL PART B COVERAGE

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$164.90
Greater than $97,000 and less than $403,000	362.60	527.50
Greater than or equal to $403,000	395.60	560.50

The monthly premium rates to be paid by (or on behalf of) beneficiaries with immunosuppressive drug only Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$97.10
Greater than $97,000 and less than $403,000	356.00	453.10
Greater than or equal to $403,000	388.40	485.50

The Part B annual deductible for 2023 is $226.00 for all beneficiaries.

TABLE 2—PROJECTION FACTORS [1]
12-MONTH PERIODS ENDING DECEMBER 31 OF 2020–2023
[In percent]

Calendar year	Physician fee schedule	Durable medical equipment	Practitioner lab [2]	Physician-administered drugs	Other practitioner services [3]	Outpatient hospital	Home health agency	Hospital lab [4]	Other institutional services [5]	Managed care
Aged:										
2020	−11.3	2.3	8.8	4.2	−0.5	−5.9	−2.2	10.7	−5.2	6.9
2021	18.6	5.6	20.2	10.9	5.1	20.3	3.7	16.3	5.8	1.3
2022	2.1	4.7	−6.9	12.4	4.8	11.5	5.3	−5.3	7.0	6.5
2023	1.0	11.4	−2.6	10.4	6.4	12.3	26.9	−8.8	7.3	6.3
Disabled:										
2020	−8.5	−0.8	−7.0	8.8	8.4	−7.7	10.5	9.7	−4.8	7.8
2021	13.1	3.6	22.4	16.8	0.2	11.5	6.6	20.4	12.9	1.6
2022	−0.9	3.7	−8.6	13.8	0.6	8.6	6.3	−5.4	7.0	7.7
2023	1.3	11.9	−2.6	10.8	6.8	13.3	31.3	−8.8	7.7	6.4

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[3] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[4] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[5] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2020 THROUGH DECEMBER 31, 2023

	CY 2020	CY 2021	CY 2022	CY 2023
Covered services (at level recognized):				
Physician fee schedule	$62.05	$69.45	$67.26	$65.53
Durable medical equipment	6.16	6.15	6.11	6.56
Practitioner lab [1]	4.54	5.15	4.55	4.27
Physician-administered drugs	17.33	18.16	19.37	20.69
Other practitioner services [2]	8.85	8.78	8.73	8.95
Outpatient hospital	45.57	51.78	54.76	59.29
Home health agency	8.12	7.95	7.94	9.71
Hospital lab [3]	2.16	2.37	2.13	1.87
Other institutional services [4]	17.36	17.34	17.59	18.19
Managed care	128.46	139.51	157.29	173.27
Total services	300.61	326.65	345.73	368.33
Cost sharing:				
Deductible	−7.56	−7.77	−8.90	−8.65
Coinsurance	−24.88	−27.68	−25.53	−24.52
Sequestration of benefits	−1.79	0.00	−3.89	−6.70
Total benefits	266.38	291.20	307.40	328.46
Administrative expenses	4.52	4.74	4.43	4.13
Incurred expenditures	270.90	295.94	311.83	332.59
Value of interest	−1.33	−1.93	−2.45	−2.93
Contingency margin for projection error and to amortize the surplus or deficit	13.63	−3.01	24.82	−5.96
Monthly actuarial rate	$283.20	$291.00	$334.20	$323.70

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2020 THROUGH DECEMBER 31, 2023

	CY 2020	CY 2021	CY 2022	CY 2023
Covered services (at level recognized):				
Physician fee schedule	$62.28	$63.52	$57.34	$53.19
Durable medical equipment	10.97	10.24	9.61	9.78
Practitioner lab [1]	5.35	5.88	4.86	4.32
Physician-administered drugs	15.53	16.28	16.74	16.88
Other practitioner services [2]	12.39	11.16	10.23	10.00
Outpatient hospital	55.57	56.30	55.41	57.16
Home health agency	6.84	6.38	6.23	7.51
Hospital lab [3]	2.53	2.73	2.34	1.95
Other institutional services [4]	48.96	41.29	39.95	40.03

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2020 THROUGH DECEMBER 31, 2023—Continued

	CY 2020	CY 2021	CY 2022	CY 2023
Managed care	149.93	178.13	212.60	244.15
Total services	370.35	391.91	415.31	444.97
Cost sharing:				
Deductible	−7.11	−7.30	−8.36	−8.14
Coinsurance	−36.24	−35.19	−29.48	−26.22
Sequestration of benefits	−2.18	0.00	−4.72	−8.21
Total benefits	324.82	349.42	372.75	402.41
Administrative expenses	5.43	5.69	8.06	7.82
Incurred expenditures	330.25	355.10	380.81	410.24
Value of interest	−1.65	−2.52	−3.53	−3.59
Contingency margin for projection error and to amortize the surplus or deficit	15.00	−2.68	−8.38	−48.75
Monthly actuarial rate	$343.60	$349.90	$368.90	$357.90

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2023

As of December 31,	2021	2022	2023
Actuarial status (in millions):			
Assets	$163,333	$192,097	$180,801
Liabilities	$32,618	$35,045	$36,786
Assets less liabilities	$130,716	$157,052	$144,015
Ratio [1]	28.6%	31.4%	26.3%
Low-cost projection:			
Actuarial status (in millions):			
Assets	$163,333	$215,623	$265,236
Liabilities	$32,618	$32,430	$34,676
Assets less liabilities	$130,716	$183,202	$230,559
Ratio [1]	30.3%	40.5%	47.6%
High-cost projection:			
Actuarial status (in millions):			
Assets	$163,333	$168,397	$127,706
Liabilities	$32,618	$37,678	$39,042
Assets less liabilities	$130,716	$130,718	$88,664
Ratio [1]	27.1%	23.8%	14.5%

[1] Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Collection of Information Requirements

This document does not impose information collection requirements—that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Analysis

A. Statement of Need

This notice announces the monthly actuarial rates and premium rates, as required by section 1839(a) of the Act, and the annual deductible, as required by section 1833(b) of the Act, for beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2023. It also responds to section 1839(a)(1) of the Act, which requires the Secretary to provide for publication of these amounts in the **Federal Register** during the September that precedes the start of each calendar year. As section 1839 of the Act prescribes a detailed methodology for calculating these amounts, we do not have the discretion to adopt an alternative approach on these issues.

B. Overall Impact

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18,

2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a notice/rule: (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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). A regulatory impact analysis (RIA) must be prepared for major rules or other regulatory documents with economically significant effects ($100 million or more in any one year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. The 2023 standard Part B premium of $164.90 is $5.20 lower than the 2022 premium of $170.10. We estimate that the total premium decrease, for the approximately 60 million Part B enrollees in 2023, will be −$3.8 billion, which is an annual effect on the economy of $100 million or more. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action as defined under the Congressional Review Act (5 U.S.C. 804(2)).

C. Detailed Economic Analysis

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2023 are $323.70 for enrollees age 65 and over and $357.90 for disabled enrollees under age 65. It also announces the 2023 monthly Part B premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns.

FULL PART B COVERAGE

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$164.90
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	65.90	230.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	164.80	329.70
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	263.70	428.60
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	362.60	527.50
Greater than or equal to $500,000	Greater than or equal to $750,000	395.60	560.50

For beneficiaries with immunosuppressive drug only Part B coverage, who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns, the 2023 Part B monthly premium rates are announced and listed in the following table:

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who file individual tax returns with modified adjusted gross income:	Beneficiaries who file joint tax returns with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	Less than or equal to $194,000	$0.00	$97.10
Greater than $97,000 and less than or equal to $123,000	Greater than $194,000 and less than or equal to $246,000	64.70	161.80
Greater than $123,000 and less than or equal to $153,000	Greater than $246,000 and less than or equal to $306,000	161.80	258.90
Greater than $153,000 and less than or equal to $183,000	Greater than $306,000 and less than or equal to $366,000	258.90	356.00
Greater than $183,000 and less than $500,000	Greater than $366,000 and less than $750,000	356.00	453.10
Greater than or equal to $500,000	Greater than or equal to $750,000	388.40	485.50

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries with full Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are also announced and listed in the following table:

FULL PART B COVERAGE

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$164.90
Greater than $97,000 and less than $403,000	362.60	527.50
Greater than or equal to $403,000	395.60	560.50

The monthly premium rates to be paid by (or on behalf of) beneficiaries with immunosuppressive drug only Part B coverage who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are announced and listed in the following table:

PART B IMMUNOSUPPRESSIVE DRUG COVERAGE ONLY

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses, with modified adjusted gross income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $97,000	$0.00	$97.10
Greater than $97,000 and less than $403,000	356.00	453.10
Greater than or equal to $403,000	388.40	485.50

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 6 we have prepared an accounting statement showing the estimated aggregate Part B premium increase for all enrollees in 2023.

TABLE 6—ACCOUNTING STATEMENT: THE ESTIMATED AGGREGATE PART B PREMIUM INCREASE FOR ALL ENROLLEES FOR 2023

Estimated Aggregate Part B Premium Increase for All Enrollees for 2023	
Category	
Annualized Monetized Transfers	−$3.8 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule or other regulatory document has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2023. Also, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule or other regulatory document may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As we discussed previously, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant effect on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The cost to each State Medicaid program from the 2023 premium decrease is estimated to be less than the threshold. This notice does not impose mandates that will have a consequential effect of the threshold amount or more on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule or other regulatory document (and subsequent final rule or other regulatory document) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal**

Register and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary of the Department of Health and Human Services (the Secretary) to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual updated amounts for the Part B monthly actuarial rates for aged and disabled beneficiaries, the Part B premium, and the Part B deductible set forth in this notice do not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule that would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1839 of the Act requires the Secretary to determine the monthly actuarial rates for aged and disabled beneficiaries, as well as the monthly Part B premium (including the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts), for each calendar year in accordance with the statutory formulae, in September preceding the year to which they will apply. Further, the statute requires that the agency promulgate the Part B premium amount, in September preceding the year to which it will apply, and include a public statement setting forth the actuarial assumptions and bases employed by the Secretary in arriving at the amount of an adequate actuarial rate for enrollees age 65 and older. We include the Part B annual deductible, which is established in accordance with a specific formula described in section 1833(b) of the Act, because the determination of the amount is directly linked to the rate of increase in actuarial rate under section 1839(a)(1) of the Act. We have calculated the monthly actuarial rates for aged and disabled beneficiaries, the Part B deductible, and the monthly Part B premium as directed by the statute; since the statute establishes both when the monthly actuarial rates for aged and disabled beneficiaries and the monthly Part B premium must be published and the information that the Secretary must factor into those amounts, we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice, and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the monthly actuarial rates for aged and disabled beneficiaries and the Part B deductible, as well as the monthly Part B premium amounts and the income-related monthly adjustment amounts to be paid by certain beneficiaries, in accordance with the statute, for CY 2023. As such, we also note that even if notice and comment procedures were required for this notice, we would find good cause, for the previously stated reason, to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1839 of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion for both the agency and Medicare beneficiaries.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 23, 2022.

Dated: September 23, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8081–N]

RIN 0938–AU72

Medicare Program; CY 2023 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

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

ACTION: Notice.

SUMMARY: This notice announces Medicare's Hospital Insurance Program (Medicare Part A) premium for uninsured enrollees in calendar year 2023. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain individuals with disabilities who have exhausted other entitlement. The monthly Medicare Part A premium for the 12 months beginning January 1, 2023 for these individuals will be $506. The premium for certain other individuals as described in this notice will be $278.

DATES: The premium announced in this notice is effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Yaminee Thaker, (410) 786–7921.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the

Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain individuals with disabilities who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and premium-free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain individuals with disabilities as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (sections 1818 and 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2022 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

Section 1818(g) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary), at the request of a state, to enter into a Medicare Part A buy-in agreement with a state to pay Medicare Part A premiums for Qualified Medicare Beneficiaries (QMBs). Under the QMB program, state Medicaid agencies must pay the Medicare Part A premium for those not eligible for premium-free Medicare Part A if those individuals meet all of the eligibility requirements for the QMB program under the state's Medicaid state plan. (Entering into a Medicare Part A buy-in agreement would permit a state to avoid any Medicare Part A late enrollment penalties that the individual may owe and would allow states to enroll persons in Medicare Part A at any time of the year, without regard to Medicare enrollment periods.) Other individuals may be eligible for the Qualified Disabled Working Individuals program, through which state Medicaid programs provide coverage for the Medicare Part A premiums of individuals eligible to enroll in Medicare Part A by virtue of section 1818A of the Act who meet certain financial eligibility criteria.

II. Monthly Premium Amount for CY 2023

The monthly premium for the uninsured aged and certain individuals with disabilities who have exhausted other entitlement for the 12 months beginning January 1, 2023, is $506. The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45 percent reduction in the monthly premium, is $278.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2023 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over, as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2023 on—(1) current historical data; and (2) projection assumptions derived from current law and the President's Fiscal Year 2023 Budget.

For CY 2023, we estimate that 57,454,122 people aged 65 years and over will be entitled to (enrolled in) benefits (without premium payment) and that they will incur about $348.957 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $506.14 and the monthly premium is $506. Subsequently, the full monthly premium reduced by 45 percent is $278.

IV. Costs to Beneficiaries

The CY 2023 premium of $506 is approximately 1.4 percent higher than the CY 2022 premium of $499. We estimate that approximately 730,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Medicare Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2023 reduced premium of $278 is approximately 1.5 percent higher than the CY 2022 premium of $274. We estimate an additional 91,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2023, compared to the amount that they paid in CY 2022, will be about $65 million.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or

changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual Medicare Part A premium announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1818(d) of the Act requires the Secretary during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. Further, the statute requires that the agency determine the applicable premium amount for each CY in accordance with the statutory formula, and we are simply notifying the public of the changes to the Medicare Part A premiums for CY 2023. We have calculated the Medicare Part A premiums as directed by the statute; the statute establishes both when the premium amounts must be published and the information that the Secretary must factor into the premium amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the Medicare Part A premiums, in accordance with the statute, for CY 2023. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1818(d) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

This notice announces the CY 2023 Medicare Part A premiums for the uninsured aged and for certain disabled individuals who have exhausted other entitlement, as required by section 1818 and 1818A of the Act. It also responds to section 1818(d) of the Act, which requires the Secretary to provide for publication of these amounts in the **Federal Register** during the September that precedes the start of each CY. As this statutory provision prescribes a detailed methodology for calculating these amounts, we do not have the discretion to adopt an alternative approach on these issues.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and

hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Medicare Part A premium will be a cost to voluntary enrollees (sections 1818 and 1818A of the Act) of about $65 million.

C. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in the Table below, we have prepared an accounting statement showing the total aggregate cost to enrollees paying premiums in CY 2023, compared to the amount that they paid in CY 2022. This amount will be about $65 million. As stated in section IV of this notice, the CY 2023 premium of $506 is approximately 1.4 percent higher than the CY 2022 premium of $499. We estimate that approximately 730,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Medicare Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2023 reduced premium of $278 is approximately 1.5 percent higher than the CY 2022 premium of $274.

TABLE—ESTIMATED TRANSFERS FOR CY 2023 MEDICARE PART A PREMIUMS

Category	Transfers
Annualized Monetized Transfers.	$65 million.
From Whom to Whom	Beneficiaries to Federal Government.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A premiums for CY 2023 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A premiums for CY 2023 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This notice would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $165 million in any 1 year.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

G. Congressional Review

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 23, 2022.

Dated: September 26, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–21176 Filed 9–27–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8080–N]

RIN 0938–AU71

Medicare Program; CY 2023 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

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

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2023 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

DATES: The deductible and coinsurance amounts announced in this notice are effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Yaminee Thaker, (410) 786 7921.

SUPPLEMENTARY INFORMATION: For CY 2023, the inpatient hospital deductible will be $1,600. The daily coinsurance amounts for CY 2023 will be: $400 for the 61st through 90th day of hospitalization in a benefit period; $800 for lifetime reserve days; and $200 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to

determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

II. Computing the Inpatient Hospital Deductible for CY 2023

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2023 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for FY 2023, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary is reduced by one quarter of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 100 percent for FY 2017 and each subsequent FY. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and are expected to receive the full market basket update.

Under section 1886 of the Act, the percentage increase used to update the payment rates (or target amounts, as applicable) for FY 2023 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by the MFP adjustment (see section 1886(m)(3)(A) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments and the site-neutral payment rates (see sections 1886(m)(5) and 1886(m)(6) of the Act).
- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(j)(7) of the Act).
- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by the MFP adjustment (see section 1886(s)(2)(A)(i) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(s)(4) of the Act).
- The percentage increase used to update the target amounts for other types of hospitals that are excluded from the inpatient prospective payment system and that are paid on a reasonable cost basis, subject to a rate-of-increase ceiling, is the inpatient prospective payment system operating market basket percentage increase, which is described at section 1886(b)(3)(B)(ii)(VIII) of the Act and 42 CFR 413.40(c)(3). These other types of hospitals include cancer hospitals, children's hospitals, extended neoplastic disease care hospitals, and hospitals located outside the 50 states, the District of Columbia, and Puerto Rico.

The inpatient prospective payment system market basket percentage increase for FY 2023 is 4.1 percent and the MFP adjustment is 0.3 percentage point, as announced in the final rule that appeared in the **Federal Register** on August 10, 2022 entitled, ''Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation'' (87 FR 49052). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 3.8 percent (that is, the FY 2023 market basket update of 4.1 percent less the MFP adjustment of 0.3 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 3.9 percent. This average includes long term care hospitals, inpatient rehabilitation facilities, and other hospitals excluded from the inpatient prospective payment system. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2023 is 3.81 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare inpatient prospective payment system in FY 2022 compared to FY 2021. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2022. These bills represent a total of about 5.4 million Medicare discharges for FY 2022 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2022 is –0.7 percent. Based on these bills and past experience, we expect the overall FY 2022 case mix change to be − 1 percent as the year progresses and more FY 2022 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case mix change that is determined to be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. COVID–19 has complicated the determination of real case-mix changes. COVID–19 cases typically have higher-weighted MS DRGs which would cause a real increase in case-mix while hospitals have experienced a reduction in lower-

weighted cases which would also cause a real increase in case-mix. The lower amount of COVID–19 cases in 2022 compared to the last several years would therefore mean a decrease in real case mix. In addition, care that was deferred in 2020 and 2021 could be more costly in 2022 causing an increase in real case-mix. Due to the uncertainty we are assuming that all of the recently observed care is not due to coding optimization and hence all of the −1 percent is real.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 3.81 percent, and the real case-mix adjustment factor for the deductible is −1 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2023 to be $1,600. This deductible amount is determined by multiplying $1,556 (the inpatient hospital deductible for CY 2022 (86 FR 64217)) by the payment-weighted average increase in the payment rates of 1.0381 multiplied by the decrease in real case-mix of 0.99, which equals $1,599.13 and is rounded to $1,600.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2023

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2023, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $400 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be $800 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility (SNF) in a benefit period will be $200 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

IV. Cost to Medicare Beneficiaries

Table 1 summarizes the deductible and coinsurance amounts for CYs 2022 and 2023, as well as the number of each that is estimated to be paid.

TABLE 1—MEDICARE PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CYS 2022 AND 2023

Type of cost sharing	Value		Number paid (in millions)	
	2022	2023	2022	2023
Inpatient hospital deductible	$1,556	$1,600	5.41	5.90
Daily coinsurance for 61st–90th day	389	400	1.32	1.43
Daily coinsurance for lifetime reserve days	778	800	0.67	0.73
SNF coinsurance	194.50	200	28.38	27.93

The estimated total increase in costs to beneficiaries is about $1,210 million (rounded to the nearest $10 million) due to: (1) the increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2022 and 2023 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual inpatient hospital deductible and the hospital and extended care services coinsurance amounts announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts between September 1 and September 15 of the year preceding the year to which they will apply. Further, the statute requires that the agency determine and publish the inpatient hospital deductible and hospital and

extended care services coinsurance amounts for each CY in accordance with the statutory formulae, and we are simply notifying the public of the changes to the deductible and coinsurance amounts for CY 2023. We have calculated the inpatient hospital deductible and hospital and extended care services coinsurance amounts as directed by the statute; the statute establishes both when the deductible and coinsurance amounts must be published and the information that the Secretary must factor into the deductible and coinsurance amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the inpatient hospital deductible and the hospital and extended care services coinsurance amounts, in accordance with the statute, for CY 2023. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1813(b)(2) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

This notice announces the Medicare Part A inpatient hospital deductible and associated coinsurance amounts for hospital and extended care services applicable for care provided in CY 2023, as required by section 1813 of the Act. It also responds to section 1813(b)(2) of the Act, which requires the Secretary to provide for publication of these amounts in the **Federal Register** between September 1 and September 15 of the year preceding the year to which they will apply. As this statutory provision prescribes a detailed methodology for calculating these amounts, we do not have the discretion to adopt an alternative approach on these issues.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $1,210 million due to: (1) the increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid.

C. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table 2, we have prepared an accounting statement showing the estimated total increase in costs to beneficiaries of about $1,210 million, which is due to the increase in the deductible and coinsurance amounts, and the increase in the number of deductibles and daily coinsurance amounts paid. As stated in section IV of this notice, we determined the increase in cost to beneficiaries by calculating the difference between the 2022 and 2023 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

TABLE 2—ESTIMATED TRANSFERS FOR CY 2023 DEDUCTIBLE AND COINSURANCE AMOUNTS

Category	Transfers
Annualized Monetized Transfers.	$1,210 million.
From Whom to Whom	Beneficiaries to Providers.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than

$8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2023 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2023 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This notice would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $165 million in any 1 year.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

G. Congressional Review

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 23, 2022.

Dated: September 26, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–21180 Filed 9–27–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10691]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 31, 2022.

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Data Request and Attestation for PDP Sponsors; *Use:* Section 50354 of the BBA requires that the Secretary establish a process for PDP sponsors to submit a request for standardized extracts of claims data for their enrollees. In addition, Section 50354 of the BBA provides for a number of purposes and limitation for the use of the claims data and also permits the Secretary to establish other limitations necessary to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

This information collection request allows a PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that

are listed in 42 CFR 423.153(g)(3) and After requesting claims data for its enrollees and attesting to the permitted uses and limitations of Medicare claims data, PDP sponsors are required to complete some basic on-boarding activities before gaining access to Medicare claims data using the Part A and B Claims Data to Part D Sponsors (AB2D) API. *Form Number:* CMS–10691 (OMB Control Number: 0938–1371); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 210; *Number of Responses:* 210; *Total Annual Hours:* 39. (For policy questions regarding this collection contact Gaare, Kari A. at 410–786–8612.)

Dated: September 26, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–21109 Filed 9–28–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–R–5]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 28, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–R–5—Physicians Certifications/Recertifications in Skilled Nursing Facilities Manual Instructions

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Physician Certifications/Recertifications in Skilled Nursing Facilities Manual Instruction; *Use:* Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA1989, Pub. L. 101–239), section 1814(a)(2) of the Act required that, in the case of posthospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF on an inpatient basis.

The Medicare program requires, as a condition for Medicare Part A payment for posthospital skilled nursing facility (SNF) services, that a physician or other authorized practitioner must certify and periodically recertify that a beneficiary requires an SNF level of care. The physician certification and recertification is intended to ensure that the beneficiary's need for services has been established and then reviewed and updated at appropriate intervals. The documentation is a condition for Medicare Part A payment for post-hospital SNF care. *Form Number:* CMS–R–5 (OMB control number 0938–0454); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 2,315,259; *Number of Responses:* 2,315,259; *Total Annual Hours:* 522,199. (For policy questions regarding this collection contact Kia Burwell at 410–786–7816).

Dated: September 26, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–21108 Filed 9–28–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; 45 CFR 303.7—Provision of Services in Intergovernmental IV–D; Federally Approved Forms (OMB #0970–0085)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement is requesting a 3-year extension of the Provision of Services in Intergovernmental IV–D; Federally Approved Forms (OMB #0970–0085, expiration December 31, 2022). There are no changes requested to these forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of 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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Public Law 113–183, the Preventing Sex Trafficking and Strengthening Families Act, amends section 466(f) of the Social Security Act requiring all states to enact any amendments to the Uniform Interstate Family Support Act ''officially adopted as of September 30, 2008, by the National Conference of Commissioners on Uniform State Laws'' (referred to as UIFSA 2008). Section 311(b) of UIFSA requires states to use forms mandated by federal law. 45 CFR 303.7(a)(4) also requires child support programs to use federally approved forms in intergovernmental IV–D cases unless a country has provided alternative forms.

Respondents: State agencies administering a child support program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Transmittal #1—Initial Request	54	16,048	0.17	147,321
Transmittal #1—Initial Request Acknowledgement	54	16,048	0.05	43,330
Transmittal #2—Subsequent Action	54	12,036	0.08	51,996
Transmittal #3—Request for Assistance/Discovery	54	2,407	0.08	10,398
Uniform Support Petition	54	6,419	0.05	17,331
General Testimony	54	6,419	0.33	114,387
Declaration in Support of Establishing Parentage	54	2,407	0.15	19,497
Child Support Locate Request	54	160	0.05	432
Notice of Determination of Controlling Order	54	2	0.25	27
Letter of Transmittal Requesting Registration	54	9,629	0.08	41,597
Personal Information Form For UIFSA § 311	54	6,419	0.05	17,331
Child Support Agency Confidential Information Form	54	19,258	0.05	51,997
Request for Change of Support Payment Location Pursuant to UIFSA 319(b)	54	80	0.05	216

Estimated Total Annual Burden Hours: 515,860.

Authority: 45 CFR 303.7.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–21041 Filed 9–28–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES'

Administration for Children and Families

[OMB No. 0970–0307]

Submission for OMB Review; State Court Improvement Program

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for Public Comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Court Improvement Program (CIP)Program Strategic Plan Template and Annual CIP Self-Assessment (Office of Management and Budget (OMB) #0970–0307, expiration November 30, 2022). There are minimal updates to the form to reflect new legislation as well as to support technical assistance. The collections are necessary to continue operating the program in compliance with congressional reauthorization.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of 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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed collection is a continuation of the current collection and comprised of two components: An application including a strategic plan and annual self-assessment. The self-assessment reflects what the state has done in the prior year focusing on its progress and status within the change management cycle. The strategic plan looks forward to those interventions and actions the state plans to undertake to address needs or buttress strengths they have discovered in their assessment activities. Additions from the prior approval include infrastructural questions around the Child and Family Services Reviews regarding efforts to engage legal and judicial staff and collaborate with the child welfare agency. They also include overall court structural questions which are responsive to requests from grantees to facilitate peer connections of similarly situated states. The next application will be due June 30, 2023.

Respondents: We anticipate the highest state court of every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands to respond. All 53 jurisdictions currently participate in the program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Self-Assessment	53	1	40	2,120
Strategic Plan	53	.20*	52	551.20
Estimated Total Annual Burden Hours:				2,671.20

*The full Strategic Plan is completed every 5 years. In years when the Strategic Plan is not completed, respondents may spend minimal time updating relevant sections of the Strategic Plan. This is accounted for in the estimate for the Annual Self-Assessment.

Authority: 42 U.S.C. 629h.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–21126 Filed 9–28–22; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Office of Community Services (OCS) Community Economic Development (CED) Standard Reporting Format (Office of Management and Budget); (OMB) #0970–0386)

AGENCY: Office of Community Services (OCS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: OCS is requesting a three-year extension of the semi-annual reporting format for CED grant recipients, the Performance Progress Report (PPR), which collects information regarding the outcomes and management of CED projects (OMB #0970–0386, expiration February 28, 2023). There are minor changes requested to the form to provide clarity to users completing the form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of 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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCS will continue collecting key information about

projects funded through the CED program. The legislative requirement for this program is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services Reauthorization Act) of October 27, 1998, Public Law 105–285, section 680(b) as amended. The PPR collects information regarding the outcomes and management of CED projects. OCS will use the data to critically review the overall design and effectiveness of the program.

The PPR will continue to be administered to all active grant recipients of the CED program. Grant recipients will be required to use this reporting tool for their semi-annual reports to be submitted twice a year. Through a previous renewal, the current PPR replaced both the annual questionnaire and other semi-annual reporting formats, which resulted in an overall reduction in burden for the grant recipients, significantly improved the quality of the data collected by OCS, and allowed grant recipients to become accustomed to this format. OCS seeks to renew this PPR to continue to collect quality data from grant recipients. To ensure the burden on grant recipients is not increased, but that the information collected demonstrates the full impact of the program, OCS has conducted an in-depth review of the forms and requests minor changes to the PPR to provide clarity to users filling out the form.

Respondents: Active CED Grant Recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
PPR for Current OCS–CED Grant Recipients	91	2	1.5	273

Estimated Total Annual Burden Hours: 273.

Authority: Section 680(a)(2) of the Community Services Block Grant (CSBG) Act, 42 U.S.C. 9921.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–21063 Filed 9–28–22; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Older Americans Act, Application for Title VI Parts A/B and C Grants OMB Control Number 0985–0064

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the information collection requirements for the Older Americans Act, Title VI Parts A/B and C Grants PPR OMB Control Number 0985–0064.

DATES: Submit written comments on the collection of information by October 31, 2022.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Jasmine Aplin, Administration for Community Living, *Jasmine.Aplin@acl.hhs.gov* (202) 795–7453.

SUPPLEMENTARY INFORMATION: This is an extension to a currently approved information collection (IC). ACL is responsible for administering the Title VI A/B (Nutrition and Supportive Service) and C (Caregiver) grants. The purpose of this data collection is to improve and standardize the format of the application. The instrument will collect data as prescribed by the Older Americans Act Section 612(a), 614(a) and 45 CFR 1326.19 related to the eligibility of Federally recognized Tribes and Native Hawaiian organizations for grant funds under this program and their capacity to deliver services to elders.

The Older Americans Act, Application for Title VI Parts A/B and C Grants collects information on the ability of federally recognized American Indian, Alaskan Native and Native Hawaiian organizations to provide nutrition, supportive, and caregiver services to elders within their service area. Applicants are required to provide a description of their organization's service area, the number of eligible elders in their service area, and their ability to deliver services and sign assurances that the organization will comply with all applicable laws and regulations.

This is an extension of a currently approved information collection. The proposed data collection materials have been updated to better align with the requirements of the Older Americans Act and Federal regulations, as well as to improve data quality and grantee accountability. Furthermore, this grantee application will better line up with the Title VI Program Performance Report under 0985–0007. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRMA).

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** *87, No. 126 on Friday, July 1, 2022*. There were No public comments in response to the 60-day notice.

Estimated Program Burden: Title VI funding is broken into three categories. Parts A and B are for nutritional and supportive programming, with Part A being restricted to American Indian and Alaska Native grantees, and Part B restricted to Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B

funding, but not all Part A/B grantees will have Part C programs. Therefore, there are likely to be 295 unique respondents, but only 250 will have to complete all three portions of the application. This application covers all three parts of Title VI.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Application Part A/B	295	1	2.75	270.4
Title VI Application Part C	250	1	1.5	125
Total			4.25	395.4

The number of burden hours associated with the Title VI, Part C, data collection was calculated as 811.25.

However, since this instrument is used only once every three years results in an annualized number of 270.4 hours. Similarly, the total hours associated with the Title VI, Part C, application is 375.

Dated: September 23, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–21080 Filed 9–28–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 28, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network (OPTN), OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by contract, provide for the establishment and operation of a private, non-profit entity the OPTN, which on behalf of HRSA, oversees the U.S. donation and transplantation system. The OPTN Board of Directors (BOD) determines what data must be collected to appropriately fulfill their responsibilities pursuant to their regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, on behalf of the OPTN BOD and in alignment with the Paperwork Reduction Act of 1995, submits OPTN BOD-approved data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop transplant, donation, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. In addition, the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The OPTN uses this information to (1) facilitate organ placement and match donor organs with recipients, (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements, (3) review and report periodically to the public on the status of organ donation and transplantation in the United States, (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation, and (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is requesting to make the following OPTN BOD-approved changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

(1) Adding data collection forms from the OPTN donor management and organ matching system to the existing OMB-approved information collection. The system allows an organ procurement organization to add donors, run the donor/potential transplant recipients matches, and place a donated organ(s) with a computer-matched potential transplant recipient. Transplant centers will access the system to view posted donor information to assist them with accepting decisions, along with other donor/potential transplant recipient functions such as entering offer responses and verifying organ offer refusals. The OPTN donor management and organ matching system is comprised of eight data collection forms:

initial donor registration, organ procurement organization notification limit administration, potential transplant recipient, death notification registration, deceased donor death referral, donor hospital registration, donor organ disposition, and transplant center contact management.

(2) The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.

(3) Existing OPTN data collection forms that collect a single race and ethnicity variable will be revised to collect separate race and ethnicity variables, following the minimum standards for collecting and presenting data on race and ethnicity for all federal reporting found within *Revisions of Standards for the Classification of Federal Data on Race and Ethnicity,* OMB Statistical Policy Directive No. 15 in **Federal Register**, 62 FR 58782 (Oct. 30, 1997). Improving data collection around race and ethnicity information of donors and candidates aligns with Executive Order 13985, which calls on agencies to advance equity through identifying and addressing barriers to equal opportunity that underserved communities may face due to government policies and programs.

Likely Respondents: Transplant programs, organ procurement organizations (OPO), and histocompatibility laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The estimated total estimated burden hours for this collection increased by 213,662 hours from the currently approved ICR package. This increase is due to the addition of eight collection forms from the OPTN donor management and organ matching system to this data collection package, specifically the burden increase from the Potential Transplant Recipient form. While the data fields collected on the Potential Transplant Recipient form are limited, the volume of organ offer responses is significant due to the large number of potential transplant recipients shown on the organ match run results. The organ match run results produce thousands of potential transplant recipients that require responses from OPOs and transplant hospitals. This volume of candidates significantly impacts the total burden hours for this form.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Deceased Donor Registration	57	243.560	13,883	1.09	15,132
Living Donor Registration	216	28.106	6,071	2.19	13,295
Living Donor Follow-up	216	90.550	19,559	1.52	29,730
Donor Histocompatibility	141	149.184	21,035	0.20	4,207
Recipient Histocompatibility	141	264.950	37,358	0.40	14,943
Heart Transplant Candidate Registration	145	34.586	5,015	0.90	4,514
Heart Transplant Recipient Registration	145	26.324	3,817	1.40	5,344
Heart Transplant Recipient Follow-Up (6 Months)	145	24.400	3,538	0.40	1,415
Heart Transplant Recipient Follow-Up (1–5 Years)	145	104.140	15,100	0.90	13,590
Heart Transplant Recipient Follow-Up (Post 5 Year)	145	171.100	24,810	0.50	12,405
Heart Post-Transplant Malignancy Form	145	13.170	1,910	0.90	1,719
Lung Transplant Candidate Registration	72	42.970	3,094	0.90	2,785
Lung Transplant Recipient Registration	72	35.010	2,521	1.20	3,025
Lung Transplant Recipient Follow-Up (6 Months)	72	33.630	2,421	0.50	1,211
Lung Transplant Recipient Follow-Up (1–5 Years)	72	139.940	10,076	1.10	11,084
Lung Transplant Recipient Follow-Up (Post 5 Year)	72	136.280	9,812	0.60	5,887
Lung Post-Transplant Malignancy Form	72	22.630	1,629	0.40	652
Heart/Lung Transplant Candidate Registration	70	0.960	67	1.10	74
Heart/Lung Transplant Recipient Registration	70	0.640	45	1.30	59
Heart/Lung Transplant Recipient Follow-Up (6 Months)	70	0.600	42	0.80	34
Heart/Lung Transplant Recipient Follow-Up (1–5 Years)	70	2.100	147	1.10	162
Heart/Lung Transplant Recipient Follow-Up (Post 5 Year)	70	3.360	235	0.60	141
Heart/Lung Post-Transplant Malignancy Form	70	0.290	20	0.40	8
Liver Transplant Candidate Registration	143	96.920	13,860	0.80	11,088
Liver Transplant Recipient Registration	143	64.580	9,235	1.20	11,082
Liver Transplant Recipient Follow-Up (6 Month–5 Year)	143	320.266	45,798	1.00	45,798
Liver Transplant Recipient Follow-Up (Post 5 Year)	143	384.320	54,958	0.50	27,479
Liver Recipient Explant Pathology Form	143	7.300	1,044	0.60	626
Liver Post-Transplant Malignancy	143	19.060	2,726	0.80	2,181
Intestine Transplant Candidate Registration	21	6.860	144	1.30	187
Intestine Transplant Recipient Registration	21	4.570	96	1.80	173
Intestine Transplant Recipient Follow-Up (6 Month–5 Year)	21	20.050	421	1.50	632
Intestine Transplant Recipient Follow-Up (Post 5 Year)	21	40.190	844	0.40	338
Intestine Post-Transplant Malignancy Form	21	0.620	13	1.00	13
Kidney Transplant Candidate Registration	234	177.000	41,418	0.80	33,134
Kidney Transplant Recipient Registration	234	105.397	24,663	1.20	29,596
Kidney Transplant Recipient Follow-Up (6 Month–5 Year)	234	517.124	121,007	0.90	108,906
Kidney Transplant Recipient Follow-Up (Post 5 Year)	234	525.103	122,874	0.50	61,437
Kidney Post-Transplant Malignancy Form	234	24.474	5,727	0.80	4,582
Pancreas Transplant Candidate Registration	120	2.650	318	0.60	191
Pancreas Transplant Recipient Registration	120	1.190	143	1.20	172

Form name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Pancreas Transplant Recipient Follow-Up (6 Month–5 Year)	120	6.680	802	0.50	401
Pancreas Transplant Recipient Follow-Up (Post 5 Year)	120	17.820	2138	0.50	1,069
Pancreas Post-Transplant Malignancy Form	120	1.060	127	0.60	76
Kidney/Pancreas Transplant Candidate Registration	120	12.450	1,494	0.60	896
Kidney/Pancreas Transplant Recipient Registration	120	6.840	821	1.20	985
Kidney/Pancreas Transplant Recipient Follow-Up (6 Month–5 Year)	120	39.440	4,733	0.50	2,367
Kidney/Pancreas Transplant Recipient Follow-Up (Post 5 Year)	120	69.410	8,329	0.60	4,997
Kidney/Pancreas Post-Transplant Malignancy Form	120	2.490	299	0.40	120
VCA Transplant Candidate Registration	21	0.330	7	0.40	3
VCA Transplant Recipient Registration	21	0.190	4	1.36	5
VCA Transplant Recipient Follow Up	21	1.000	21	1.31	28
Organ Labeling and Packaging	57	247.720	14,120	0.18	2,542
Organ Tracking and Validating	308	19.487	6,002	0.08	480
Kidney Paired Donation Candidate Registration	159	1.200	191	0.29	55
Kidney Paired Donation Donor Registration	159	1.560	248	1.08	268
Kidney Paired Donation Match Offer Management	159	1.520	242	0.67	162
Disease Transmission Event	308	1.810	557	0.62	345
Living Donor Event	251	0.155	39	0.56	22
Safety Situation	449	0.600	269	0.56	151
Potential Disease Transmission	57	8.720	497	1.27	631
Request to Unlock Form	449	42.399	19,037	0.02	381
Initial Donor Registration	57	335.720	19,136	3.00	57,408
OPO Notification Limit Administration	57	0.490	28	0.17	5
Potential Transplant Recipient	308	4,718.480	1,453,292	0.05	72,665
Death Notification Registration	57	185.770	10,589	0.42	4,447
Deceased Donor Death Referral	57	53.840	3,069	0.50	1,535
Donor Hospital Registration	57	0.040	2	0.08	0
Donor Organ Disposition	57	335.720	19,136	0.17	3,253
Transplant Center Contact Management	251	637.500	160,013	0.06	9,601
Total = 70 forms	9,146		2,352,736		643,929

* The numbers of respondents and the numbers of total responses in the burden table were updated with 2021 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Hospitals, OPO, and Histocompatibility Labs).

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's and the OPTN's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–21119 Filed 9–28–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Recourses and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 87 FR 229–230 dated January 4, 2022). This reorganization updates the functions of the Provider Relief Bureau (RD).

Chapter RD—Provider Relief Bureau

Section RD.10 Organization

Delete the organization for the Provider Relief Bureau (RD) in its entirety and replace with the following:

The Provider Relief Bureau (RD) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Provider Relief Bureau includes the following components:

(1) Office of the Associate Administrator (RD);

(2) Division of Customer Support (RD2);

(3) Division of Program Operations (RD4);

(4) Division of Data Analytics (RD5); and

(5) Division of Program Integrity (RD6).

Section RD.20 Function

Delete the functional statement for the Provider Relief Bureau (RD) in its entirety and replace with the following:

Provider Relief Bureau (RD)

The Provider Relief Bureau (PRB) ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the United States to prevent, prepare for, and respond to coronavirus. PRB reimburses health care providers for health care-related expenses or lost revenues attributable to coronavirus and provides claims reimbursement for health care entities for COVID–19 testing, treatment, and vaccine administration for uninsured and under insured individuals.

Office of the Associate Administrator (RD)

The Office of the Associate Administrator (OAA) provides overall leadership, direction, coordination, and planning in support of the programs

designed to make payments to health care providers for expenses and lost revenue related to COVID–19 and to reimburse health care entities' claims for COVID–19 testing, treatment and/or vaccine administration of uninsured and under insured individuals, helping to ensure a sustained, robust health care system. The Office: (1) guides and directs the development of policy priorities for the allocation of payments and claims reimbursements and ensures the proper management of programs; (2) leads the Bureau's administrative and management functions; (3) coordinates and tracking the development policies to ensure consistency across the Bureau, leads Bureau efforts to analyze issues arising from legislation, budget proposals, regulatory actions, and other program or policy actions; keep Congress apprised of programs and activities as necessary; (4) engagements and audits with the Government Accountability Office and the Department of Health and Human Services' Office of Inspector General; and (5) develops and leads the communications strategy for PRB's direct provider payment and claims reimbursement programs with both broad and targeted tactics.

Division of Customer Support (RD2)

The Division of Customer Support serves as the organizational focal point for PRB's centralized, comprehensive customer service function to respond to inquiries and support recipients or potential recipients of program funds, as well as stakeholders for all PRB programs. The Division is responsible for the process and adjudication of appeals and disputes brought forward from recipients of program funds.

Division of Program Operations (RD4)

The Division of Program Operations is responsible for the program operations lifecycle, from creation to reporting, for all PRB direct provider payment and claims reimbursement programs. This Division is integral in collaborating internally and with other federal partners to assist efforts that combat fraud, waste, and abuse and supporting program integrity and assessment efforts related to these programs.

Division of Data Analytics (RD5)

The Division of Data Analytics is responsible for the collection, management, and analysis of the data needed for all PRB programs, as well as the quality and evaluation of program data, with the goal of fostering transparency of program impact and outcomes. The Division maintains data and analytic capabilities to inform policy decisions and support program functions, as well as develops and manages program data strategy, analyses, and information sharing.

Division of Program Integrity (RD6)

The Division of Program Integrity is responsible for ensuring the overall integrity of PRB programs and payments made. Specifically, the Division develops and manages Bureau-wide program and payment integrity strategies, as well as evaluates provider compliance with laws, regulations, and program terms and conditions.

Section RD.30 Delegation of Authority

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed, provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

(Authority: 44 U.S.C. 3101)

Diana Espinosa,

Deputy Administrator.

[FR Doc. 2022–19941 Filed 9–28–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Nurse Corps Loan Repayment Program; OMB No. 0915–0140 Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 28, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Nurse Corps Loan Repayment Program (Nurse Corps LRP), OMB No. 0915–0140—Extension.

Abstract: The Nurse Corps LRP assists in the recruitment and retention of professional Registered Nurses (RNs), including Advanced Practice Registered Nurses (APRNs), by decreasing the financial barriers associated with pursuing a nursing education. RNs in this instance include APRNs (*e.g.,* nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, and clinical nurse specialists) dedicated to working at eligible health care facilities with a critical shortage of nurses (*i.e.,* a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing. The Nurse Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private Critical Shortage Facility or in an eligible, accredited school of nursing.

Need and Proposed Use of the Information: Individuals must submit an application in order to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant's eligibility to participate in the Nurse Corps LRP. This information collection is used by the Nurse Corps program to make award decisions about Nurse Corps LRP applicants and to monitor a participant's compliance with the program's service requirements. The Nurse Corps LRP is requesting an extension and is seeking to use the previously approved forms.

Likely Respondents: Professional RNs or APRNs who are interested in participating in the Nurse Corps LRP, and official representatives at their service sites.

Burden Statement: Burden in this context means the time expended by

persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Corps LRP Application *	7,100	1	7,100	2.00	14,200
Authorization to Release Information Form **	7,100	1	7,100	.10	710
Employment Verification Form **	7,100	1	7,100	.10	710
Disadvantaged Background Form	450	1	450	.20	90
Confirmation of Interest Form	500	1	500	.20	100
Total for Applicants	22,250		22,250		15,810

* The burden hours associated with this instrument account for both new and continuation applications. Additional (uploaded) supporting documentation is included as part of this instrument and reflected in the burden hours.
** The same respondents are completing these instruments.

The estimates of reporting for Participants are as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Semi-Annual In Service Verification Form	500	2	1,000	.50	500
Nurse Corps Critical Shortage Facility Verification Form	500	1	500	.10	50
Nurse Corps Nurse Faculty Employment Verification Form	450	1	450	.20	90
Total for Participants	1,450		1,950		640
Total for Applicants and Participants	23,700		24,200		16,450

* The 16,575 figure is a combination of burden hours for applicants and participants. This revision adds an additional form (the Disadvantaged Background Form).

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–21156 Filed 9–28–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Wednesday, October 19, 2022 from 10:00 a.m. until 4:00 p.m., and Thursday, October 20, 2022, from 10:00 a.m. until 4:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website when this information becomes available. See *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

ADDRESSES: This meeting will be held virtually and videocast. Members of the public may also submit public comment for the meeting. Instructions for submitting public comment will be posted one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or

associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment. The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 10:00 a.m., on Wednesday, October 19, 2022, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of the impact of social media use by research subjects; this will be followed by the review and potential amendment of previously approved SACHRP recommendations on the ethical and regulatory considerations for the use of artificial intelligence in human subjects research. The second day, Thursday, October 20th, is reserved for upcoming agenda items; for the full and updated meeting agenda, see *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.* The meeting will adjourn by 4:00 p.m. October 20th, 2022.

The public may submit written public comment in advance which will be circulated to committee members and may be read aloud during the meeting. Individuals submitting written public comment should submit their comments to SACHRP at *SACHRP@hhs.gov* by midnight October 14th, 2022, ET.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

[FR Doc. 2022–21163 Filed 9–28–22; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Macromolecular Structure and Function A Study Section, October 25, 2022, 08:30 a.m. to October 26, 2022, 06:00 p.m., American Inn of Bethesda, 8130 Wisconsin Ave., Bethesda, MD, 20814 which was published in the **Federal Register** on September 22, 2022, 87 FR 57917, Doc 2022–20563.

This meeting is being amended to change the location from the American Inn of Bethesda, 8130 Wisconsin Ave., Bethesda, MD 20814, to The Melrose Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037. The meeting is closed to the public.

Dated: September 23, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–21082 Filed 9–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Instrumentation and Systems Development Study Section, October 4, 2022, 6:30 a.m. to October 5, 6:00 p.m., Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814, which was published in the **Federal Register** on September 07, 2022, 87 FR 54706, Doc 2022–19211.

This meeting is being amended to change the start time from 6:30 a.m. to 8:00 a.m. and the name of the hotel from the Doubletree Hotel Bethesda to The Bethesdan Hotel, Tapestry Collection by Hilton. The address remains unchanged. The meeting is closed to the public.

Dated: September 22, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–21081 Filed 9–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) 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: National Institute of Environmental Health Sciences Special Emphasis Panel; Time Sensitive Research Opportunities in the Environmental Health Sciences.

Date: October 14, 2022.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Science, Research Triangle Park, NC 27709, *worth@niehs.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Environmental Health Sciences (EHS) Training, Member Conflict Review.

Date: November 9, 2022.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund

Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS.)

Dated: September 23, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–21111 Filed 9–28–22; 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 10(d) 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; PAR–20–131: Mammalian Models for Translational Research.

Date: October 26, 2022.

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: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Neurodegeneration Study Section.

Date: October 27–28, 2022.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301–435–1203, *laurent.taupenot@nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Prevention Study Section.

Date: October 27, 2022.

Time: 9:00 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: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, (301) 594–7945, *kotliars@mail.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neuronal Communications Study Section.

Date: October 27–28, 2022.

Time: 9:00 a.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: Prithi Rajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *prithi.rajan@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: October 27–28, 2022.

Time: 9:00 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: Jennifer Kielczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *jennifer.kielczewski@nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Emerging Imaging Technologies and Applications Study Section.

Date: October 27–28, 2022.

Time: 9:00 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: Lawrence Edward Kagemann, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–6849, *larry.kagemann@nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Immunity and Host Defense Study Section.

Date: October 27–28, 2022.

Time: 9:30 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: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4203, Bethesda, MD 20892, (301) 435–3566, *mulkya@mail.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Cell Structure and Function 1 Study Section.

Date: October 27–28, 2022.

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: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301.402.3717, *jessica.smith6@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fogarty International Research Training Award in Chronic, Non-Communicable Diseases and Disorders Across the Lifespan.

Date: October 27, 2022.

Time: 12:00 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: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Interoception and Chemosensation Study Section.

Date: October 28, 2022.

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: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.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: September 23, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–21083 Filed 9–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, October 18, 2022, 9 a.m. to October 19, 2022, 6 p.m., Marriott North Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852 which was published in the **Federal Register** on September 16, 2022, FR Doc 2022–20094 87 FR 56967.

The meeting location has changed from the Marriott North Conference Center at 5701 Marinelli Road, North Bethesda, MD 20852 to Tysons Corner Marriott, 8028 Leesburg Pike, Tysons Corner, VA 22182. The meeting date and time remains the same. The meeting is closed to the public.

Dated: September 23, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–21112 Filed 9–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2022–0018; OMB No. 1660–0024]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Federal Assistance for Offsite Radiological Emergency Preparedness and Planning

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA). In accordance with the PRA, this notice seeks comments concerning all information collections related to FEMA's Radiological Emergency Preparedness Program requirements.

DATES: Comments must be submitted on or before October 31, 2022.

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 or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Renae Connell, Emergency Management Specialist, FEMA/NPD/THD, at (202) 212–7913 or *Renae.Connell@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA's Radiological Emergency Preparedness (REP) Program coordinates the National effort to provide State, Tribal and local governments with relevant and executable planning, training, technical assistance, exercise guidance, and policies necessary to ensure that adequate capabilities exist to prepare for, respond to, and recover from incidents involving commercial nuclear power plants (NPPs). The REP Program assists State, Tribal and local governments in the development and conduct of off-site emergency planning and preparedness activities within the emergency planning zones (EPZs) of Nuclear Regulatory Commission (NRC)-licensed commercial nuclear power facilities.

Sec. 109 of the NRC Authorization Act of 1980 (Pub. L. 96–295) directed the NRC to establish emergency preparedness as a criterion for licensing commercial NPPs. Specifically, Public Law 96–295 § 109 directed the NRC to establish through rulemaking, (a) standards, developed with FEMA, for the evaluation of State and local government radiological emergency planning and preparedness; and (b) a requirement that the NRC will issue operating licenses. Before issuing a license, the NRC must determine that there is (i) a State or local emergency response plan compliant with the standards developed with FEMA or (ii) in the absence of such a plan, a State, local, or utility emergency response plan that provides reasonable assurance that public health and safety is not endangered by the NPP's operation. *See* Public Law 96–295, 109 (b)(1)(A)–(B)). The NRC revised its regulations in Part 50 of Title 10 of the CFR to incorporate additional emergency preparedness requirements, including 16 planning standards for onsite and offsite emergency plans as required by Public Law 96–295. FEMA mirrors these 16 planning standards in part 350, specifically at 44 CFR 350.5.

In the communities surrounding commercial NPP, 44 CFR 350.5(b) directs FEMA's REP Program to review offsite radiological emergency plans and preparedness. In addition, 44 CFR 350.9 describes the exercise process and requirements that States, together with all appropriate local governments, must conduct a joint exercise of that State plan, involving full participation of appropriate local government entities, the State and the appropriate licensee of the NRC. Approved plans and preparedness ''must be determined to adequately protect the public health and safety by providing reasonable assurance that appropriate protective measures can be taken offsite in the event of a radiological emergency.''

FEMA defines reasonable assurance as a determination that State, Tribal, local, and utility offsite plans and preparedness are adequate to protect public health and safety in the EPZ of commercial NPP. FEMA will consider plans, procedures, personnel, training, facilities, equipment, drills, and exercises, which in its professional judgment are critical for effective implementation of protective measures offsite in the event of any incident at a commercial NPP. FEMA will make its adequacy determination, supported by other Federal agencies, as necessary, by conducting inspections, providing Staff Assistance Visits (SAVs), organizing, conducting and reviewing training, participating in, observing and evaluating drills and exercises, and by being an engaged partner with Federal, State, Tribal, and local government officials and industry stakeholders.

State, Tribal, or local government participation in offsite radiological emergency planning and preparedness is voluntary. However, participation in the REP planning and preparedness process necessitates adherence to the program requirements as set forth in 44 CFR part 350, the joint NRC/FEMA document NUREG–0654/FEMA–REP–1, Rev. 2, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' and supplements, (*See* 84 FR 70399, December 23, 2019), and the REP Program Manual (RPM). The RPM consolidates many of the REP Program's

operative guidance and policy documents into one location and provides guidance that interprets the planning standards and evaluation criteria contained in NUREG–0654 and 44 CFR part 350. *See* FEMA P–1028, December 2019.

As part of our collection to fulfill one of FEMA's missions, each instrument is required for the performance of duties related to the mission. Therefore, due to the maturity of the program and the opportunity to reduce burden cost, there is an opportunity to consolidate, improve, or remove collection instruments. Consequently, the collection instrument in 44 CFR 350.9(c) was added to collect information and relieve requests from the exercise schedule outlined in 44 CFR 350.9. Additionally, to further reduce burden cost, the collection in 44 CFR 352.4 has been removed as it currently does not require approval under the Paperwork Reduction Act, with FEMA only receiving one or no responses in a given year.

This proposed information collection previously published in the **Federal Register** on June 7, 2022, at 87 FR 34699 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Federal Assistance for Offsite Radiological Emergency Preparedness and Planning.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0024.

FEMA Forms: There are no forms for this collection; rather the regulatory text details the content in which information is transmitted to FEMA.

Abstract: The intent of this request is the collection of comments on an extension, with change, of a currently approved information collection an OMB control number representing all information collections related to FEMA REP Program requirements described in 44 CFR parts 350 and 352.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 104.

Estimated Number of Responses: 104.

Estimated Total Annual Burden Hours: 3,400.

Estimated Total Annual Respondent Cost: $223,176.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $652,598.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate 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) enhance the quality, utility, and clarity of the information to be collected; and (d) 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 responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2022–21165 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–21–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2276]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before December 28, 2022.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2276, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Ketchikan Gateway Borough, Alaska and the Cities of Ketchikan and Saxman Project: 14–10–0603S Preliminary Date: August 28, 2020	
Ketchikan Gateway Borough	Ketchikan Gateway Borough Planning and Community Development Office, 1900 1st Avenue, Suite 126, Ketchikan, AK 99901.

[FR Doc. 2022–21142 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65. The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Colorado:					
Arapahoe (FEMA Docket No.: B–2244).	City of Aurora (21–08–1079P).	The Honorable Mike Coffman, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Public Works Department, 15151 East Alameda Parkway, Aurora, CO 80012.	Sep. 2, 2022	080002
Arapahoe (FEMA Docket No.: B–2239).	City of Centennial (21–08–0915P).	The Honorable Stephanie Piko, Mayor, City of Centennial, 13113 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 7437 South Fairplay Street, Centennial, CO 80112.	Sep. 2, 2022	080315
Arapahoe (FEMA Docket No.: B–2239).	City of Centennial (22–08–0055P).	The Honorable Stephanie Piko, Mayor, City of Centennial, 13113 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 7437 South Fairplay Street, Centennial, CO 80112.	Sep. 2, 2022	080315
Arapahoe (FEMA Docket No.: B–2239).	Unincorporated areas of Arapahoe County (21–08–0915P).	The Honorable Nancy Jackson, Chair, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120.	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.	Sep. 2, 2022	080011
Douglas (FEMA Docket No.: B–2239).	Town of Castle Rock (21–08–0797P).	The Honorable Jason Gray, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Stormwater Department, 175 Kellogg Court, Castle Rock, CO 80109.	Aug. 26, 2022	080050
Douglas (FEMA Docket No.: B–2239).	Town of Parker (21–08–0915P).	The Honorable Jeff Toborg, Mayor, Town of Parker, 20120 East Main Street, Parker, CO 80138.	Public Works and Engineering Department, 20120 East Main Street, Parker, CO 80138.	Sep. 2, 2022	080310
Douglas (FEMA Docket No.: B–2239).	Unincorporated areas of Douglas County (21–08–0545P).	The Honorable Lora A. Thomas, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Public Works Department, Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	Sep. 2, 2022	080049
Larimer (FEMA Docket No.: B–2244).	Unincorporated areas of Larimer County (21–08–0460P).	The Honorable John Kefalas, Chair, Larimer County Board of Commissioners, 200 West Oak Street, Suite 2200, Fort Collins, CO 80521.	Larimer County Engineering Department, 200 West Oak Street, Suite 3000, Fort Collins, CO 80521.	Aug. 18, 2022	080101
Florida:					
Monroe (FEMA Docket No.: B–2244).	Village of Islamorada (22–04–1253P).	The Honorable Pete Bacheler, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	Sep. 1, 2022	120424
Monroe (FEMA Docket No.: B–2244).	Village of Islamorada (22–04–2190P).	The Honorable Pete Bacheler, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	Aug. 29, 2022	120424
Orange (FEMA Docket No.: B–2239).	City of Orlando (20–04–1937P).	The Honorable Buddy W. Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32801.	Public Works Department, 400 South Orange Avenue, 8th Floor, Orlando, FL 32801.	Aug. 29, 2022	120186
Orange (FEMA Docket No.: B–2239).	Unincorporated areas of Orange County (20–04–1937P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Public Works Department, Stormwater Management Division, 4200 South John Young Parkway, Orlando, FL 32839.	Aug. 29, 2022	120179
Osceola (FEMA Docket No.: B–2239).	City of St. Cloud (21–04–5676P).	William Sturgeon, City of St. Cloud, Manager, 1300 9th Street, St. Cloud, FL 34769.	Building Department, 1300 9th Street, St. Cloud, FL 34769.	Aug. 19, 2022	120191
Osceola (FEMA Docket No.: B–2244).	Unincorporated areas of Osceola County (21–04–4047P).	Don Fisher, Osceola County Manager, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Public Works Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	Sep. 2, 2022	120189
Osceola (FEMA Docket No.: B–2239).	Unincorporated areas of Osceola County (21–04–5676P).	Don Fisher, Osceola County Manager, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Public Works Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	Aug. 19, 2022	120189
Pinellas (FEMA Docket No.: B–2239).	City of Madeira Beach (22–04–1911P).	The Honorable John Hendricks, Mayor, City of Madeira Beach, 300 Municipal Drive, Madeira Beach, FL 33708.	Community Development Department, 300 Municipal Drive, Madeira Beach, FL 33708.	Aug. 18, 2022	125127
Georgia:					
Columbia (FEMA Docket No.: B–2239).	Unincorporated areas of Columbia County (22–04–0098P).	The Honorable Douglas R. Duncan, Jr., Chair, Columbia County Board of Commissioners, P.O. Box 498, Evans, GA 30809.	Columbia County Engineering Services Department, 630 Ronald Reagan Drive, Building A, Evans, GA 30809.	Aug. 18, 2022	130059
Gwinnett (FEMA Docket No.: B–2244).	Unincorporated areas of Gwinnett County (21–04–5535P).	The Honorable Nicole Love Hendrickson, Chair, Gwinnett County Board of Commissioners, 75 Langley Drive, Lawrenceville, GA 30046.	Gwinnett County Department of Water Resources, 684 Winder Highway, Lawrenceville, GA 30045.	Aug. 18, 2022	130322

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Maryland: Montgomery (FEMA Docket No.: B–2239).	Unincorporated areas of Montgomery County (21–03–1260P).	The Honorable Marc Elrich, Montgomery County Executive, 101 Monroe Street, 2nd Floor, Rockville, MD 20850.	Montgomery County Permitting Services Department, 2425 Reedie Drive, 7th Floor, Wheaton, MD 20902.	Aug. 23, 2022	240049
Pennsylvania: Chester (FEMA Docket No.: B–2244).	Township of West Pikeland (21–03–1172P).	The Honorable Carin Mifsud, Chair, Township of West Pikeland Board of Supervisors, 1645 Art School Road, Chester Springs, PA 19425.	Township Hall, 1645 Art School Road, Chester Springs, PA 19425.	Aug. 25, 2022	421151
Texas:					
Bexar (FEMA Docket No.: B–2244).	Unincorporated areas of Bexar County (22–06–0280P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214.	Aug. 29, 2022	480035
Dallas (FEMA Docket No.: B–2244).	City of Dallas (21–06–2894P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Oak Cliff Municipal Center, 320 East Jefferson Boulevard, Room 312, Dallas, TX 75203.	Aug. 22, 2022	480171
Smith (FEMA Docket No.: B–2239).	City of Tyler (21–06–2507P).	The Honorable Don Warren, Mayor, City of Tyler, P.O. Box 2039, Tyler, TX 75710.	Development Department, 423 West Ferguson Street, Tyler, TX 75702.	Aug. 31, 2022	480571
Tarrant (FEMA Docket No.: B–2239).	City of Fort Worth (21–06–1993P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	Aug. 29, 2022	480596
Tarrant (FEMA Docket No.: B–2239).	City of Fort Worth (21–06–2476P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	Aug. 25, 2022	480596
Tarrant (FEMA Docket No.: B–2244).	City of Haslet (21–06–2045P).	The Honorable Gary Hulsey, Mayor, City of Haslet, 101 Main Street, Haslet, TX 76052.	City Hall, 101 Main Street, Haslet, TX 76052.	Sep. 6, 2022	480600
Tarrant (FEMA Docket No.: B–2244).	Unincorporated areas of Tarrant County (21–06–2045P).	The Honorable B. Glen Whitley, Tarrant County Judge, 100 East Weatherford Street, Fort Worth, TX 76196.	Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196.	Sep. 6, 2022	480582
Williamson (FEMA Docket No.: B–2244).	Unincorporated areas of Williamson County (21–06–3275P).	The Honorable Bill Gravell, Jr., Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	Sep. 1, 2022	481079

[FR Doc. 2022–21145 Filed 9–28–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–0050]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: In accordance with the Paperwork Reductions Act (PRA) of 1995 the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance. This information collection was previously published in the **Federal Register** on July 25, 2022, allowing for a 60-day comment period. ICE received no comments in connection with the 60-day notice. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until October 31, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of the 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: If you have questions related to this collection please contact: Sharon Snyder, Unit Chief, Policy and Response Unit, Student and Exchange Visitor Program, email *sevp@ice.dhs.gov,* telephone: 703–603–3400. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Comments

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 responses. ICE is adjusting the burden figures from the 60-day notice based on better estimates of the number of applications received.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households; Farms; Business or other for-profit; Not-for-profit institutions; State, local or Tribal governments; The information collection garners qualitative customer and stakeholder feedback in an efficient and timely manner, in accordance with the Administration's commitment to improving service delivery. 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 provides insights into customer or stakeholder perceptions, experiences and expectations, provides an early warning of issues with service, or focuses attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance provides useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

(5) *An estimate of the total number of respondents and the time to respond:* 130,000 responses at 5 minutes (0.0833 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 10,790 annual burden hours.

Dated: September 26, 2022.

Scott Elmore,

PRA Clearance Officer.

[FR Doc. 2022–21092 Filed 9–28–22; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6347–N–01]

The Performance Review Board

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice of appointments.

SUMMARY: The Department of Housing and Urban Development announces the establishment of the Departmental Performance Review Board (PRB) to make recommendations to the appointing authority on the performance and compensation of its Senior Executive Service (SES), Senior Level (SL) and Senior Technical (ST) professionals. This notice lists the persons that may be named to serve on the PRB from 2022 to 2024.

FOR FURTHER INFORMATION CONTACT: Selina M. Swales, Director, Office of Executive Resources, Department of Housing and Urban Development, Washington, DC 20410, telephone (202) 402–3450. (This is not a toll-free number). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The following persons may be named to serve on the PRB from 2022 to 2024. They are listed by type of appointment, name, and official title.

Name	Official title
CAREER SES	
BETTS, SUSAN A	DEPUTY ASSISTANT SECRETARY FOR FINANCE AND BUDGET.
BLOM, DOMINQUE G	GENERAL DEPUTY ASSISTANT SECRETARY FOR PUBLIC AND INDIAN HOUSING.
BOHLING, GAYLE E	DEPUTY GENERAL COUNSEL FOR OPERATIONS.
BROWN, AMY L	DEPUTY GENERAL COUNSEL FOR HOUSING PROGRAMS.
BRYON, JEMINE A	DEPUTY ASSISTANT SECRETARY FOR SPECIAL NEEDS PROGRAMS.
CLEMMENSEN, CRAIG T	DIRECTOR, DEPARTMENTAL ENFORCEMENT CENTER.
COOKE JR., KEVIN R	CHIEF FOIA AND PRIVACY OFFICER.
COOPER-JONES, BARBARA	SENIOR VICE PRESIDENT, OFFICE OF ENTERPRISE DATA AND TECHNOLOGY SOLUTIONS.
CORSIGLIA, NANCY E	SENIOR ADVISOR.
DAUGHERTY, JOHN T	SENIOR VICE PRESIDENT, OFFICE OF SECURITY.
DAVIS, THOMAS R	DIRECTOR, OFFICE OF RECAPITALIZATION AND DEVELOPMENT.
DRAYNE, MICHAEL R	SENIOR VICE PRESIDENT, STRATEGIC PLANNING AND MANAGEMENT.
FERRY, SHYLON C	DEPUTY ASSISTANT SECRETARY FOR OPERATIONS.
FLEMING-SCOTT, JIMMY	DEPUTY CHIEF PROCUREMENT OFFICER.
FERERO, JAIME E	GENERAL DEPUTY ASSISTANT SECRETARY FOR FAIR HOUSING AND EQUAL OPPORTUNITY.
FORRESTER, ALTHEA M	ASSOCIATE GENERAL COUNSEL FOR ASSISTED HOUSING AND COMMUNITY DEVELOPMENT.
FRECHETTE, HEIDI J	DEPUTY ASSISTANT SECRETARY FOR NATIVE AMERICAN PROGRAMS.
GAITHER, FELICIA R	DEPUTY ASSISTANT SECRETARY FOR FIELD OPERATIONS.
GETCHIS, JOHN F	SENIOR VICE PRESIDENT, OFFICE OF CAPITAL MARKETS.
GOLRICK, JANET A	CHIEF DISASTER AND NATIONAL SECURITY OFFICER.

Name	Official title
HADLEY, JOY L	DIRECTOR, OFFICE OF LENDER ACTIVITIES AND PROGRAMS.
HALLIDAY, TOBIAS	DIRECTOR, OFFICE OF ASSET MANAGEMENT AND PORTFOLIO OVERSIGHT.
IJAZ, SAIRAH R	ASSISTANT CHIEF FINANCIAL OFFICER FOR SYSTEMS (FY23).
JOHNSON, CALVIN C	DEPUTY ASSISTANT SECRETARY FOR THE OFFICE OF RESEARCH, EVALUATION AND MONITORING.
KEITH, GREGORY A	SENIOR VICE PRESIDENT AND CHIEF RISK OFFICER.
KOME, JESSE A	DIRECTOR, OFFICE OF BLOCK GRANT ASSISTANCE (FY23).
KORNEGAY, EMILY M	ASSISTANT CHIEF FINANCIAL OFFICER FOR BUDGET.
KUBACKI, MELAJO K	ASSISTANT CHIEF FINANCIAL OFFICER FOR FINANCIAL MANAGEMENT.
LOFINMAKIN, ADETOKUNBO	SENIOR VICE PRESIDENT AND CHIEF FINANCIAL OFFICER.
MONTGOMERY, MATISHA D	CHIEF LEARNING OFFICER (FY23).
MORRIS, VANCE T	ASSOCIATE GENERAL DEPUTY ASSISTANT SECRETARY FOR HOUSING.
NGUYEN, NHEIN T	CHIEF PERFORMANCE OFFICER (FY23).
NIGAM, NITA	ASSISTANT CHIEF FINANCIAL OFFICER FOR ACCOUNTING.
PAO, JEAN LIN	DIRECTOR, OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION.
PARKER, TENILLE S	DIRECTOR, DISASTER RECOVERY SPECIAL ISSUES DIVISION (FY23).
PORDZIK, LESLIE A	SENIOR VICE PRESIDENT, MORTGAGED BACKED SECURITIES.
PRESTON, TAWANNA A	SENIOR VICE PRESIDENT OF ADMINISTRATION AND SENIOR ADVISOR TO OFFICE OF THE PRESIDENT.
RICHARDSON, TODD M	GENERAL DEPUTY ASSISTANT SECRETARY FOR POLICY DEVELOPMENT AND RESEARCH.
ROBINSON, JOZETTA M	EXECUTIVE SECRETARIAT (FY23).
SANTA ANNA, AARON	ASSOCIATE GENERAL COUNSEL FOR LEGISLATION AND REGULATIONS (FY23).
SAUNDERS, ELISSA O	DIRECTOR, OFFICE OF SINGLE-FAMILY HOUSING PROGRAMS DEVELOPMENT.
SCOTT, PAUL A	BUSINESS CHANGE AND INTEGRATION OFFICER.
WEBBER, CHRISTOPHER S	PRINCIPAL DEPUTY CHIEF INFORMATION OFFICER.
SANTA ANNA, AARON	ASSOCIATE GENERAL COUNSEL FOR LEGISLATION AND REGULATIONS (FY23).
SAUNDERS, ELISSA O	DIRECTOR, OFFICE OF SINGLE-FAMILY HOUSING PROGRAMS DEVELOPMENT.
SCOTT, PAUL A	BUSINESS CHANGE AND INTEGRATION OFFICER.
WEBBER, CHRISTOPHER S	PRINCIPAL DEPUTY CHIEF INFORMATION OFFICER.
NON-CAREER SES	
BROWN, VICTORIA C	DEPUTY CHIEF OF STAFF.
BRUNDAGE, SARAH J	SENIOR ADVISOR FOR HOUSING SUPPLY CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS.
CARLILE, JOSEPH W	SENIOR ADVISOR BUDGET-POLICY AND PROGRAMS.
CHO, RICHARD S	SENIOR ADVISOR.
GREENE, SOLOMON	PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR POLICY DEVELOPMENT AND RESEARCH.
HANDELMAN, ETHAN D	DEPUTY ASSISTANT SECRETARY FOR MULTIFAMILY HOUSING.
JONES, JENNIFER C	CHIEF OF STAFF.
JOSEPH, JULIENNE Y	DEPUTY ASSISTANT SECRETARY FOR SINGLE-FAMILY HOUSING.
KEEGAN, ROBIN K	DEPUTY ASSISTANT SECRETARY FOR ECONOMIC DEVELOPMENT.
KLUBES, BENJAMIN	PRINCIPAL DEPUTY GENERAL COUNSEL.
MCCAIN, DEMETRIA L	PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR FAIR HOUSING AND EQUAL OPPORTUNITIES.
MCFADDEN, MARION	PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR COMMUNITY PLANNING AND DEVELOPMENT.
METRAKAS, EUGENIA M	CHIEF OPERATIONS OFFICER.
NIBLOCK, ELIZABETH A	CHIEF INFORMATION OFFICER.
PITTMAN, MIA N	DEPUTY ASSISTANT SECRETARY FOR RISK MANAGEMENT AND REGULATORY AFFAIRS.
PEREZ, MICHELE P	ASSISTANT DEPUTY SECRETARY FOR FIELD POLICY AND MANAGEMENT.
SAMBERG-CHAMPION, SASHA M	DEPUTY GENERAL COUNSEL FOR ENFORCEMENT.
TAYLOR, PATRICE D	DEPUTY CHIEF OF STAFF.
VALVERDE, SAM I	EXECUTIVE VICE PRESIDENT AND CHIEF OPERATING OFFICER.

Adrianne R. Todman,

Deputy Secretary.

[FR Doc. 2022–21160 Filed 9–28–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2022–0137; FXIA16710900000–223–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by October 31, 2022.

ADDRESSES: *Obtaining Documents:* The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2022–0137.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and

submit comments on Docket No. FWS–HQ–IA–2022–0137.

• *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2022–0137; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* 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:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: Denver Zoological Foundation, Denver, CO; Permit No. PER0052800

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Asian elephant (*Elephas maximus*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Yale University Peabody Museum of Natural History, New Haven, CT; Permit No. PER0052084

The applicant requests the renewal and amendment of their permit to export and re-import non-living museum and herbarium specimens of endangered and threatened species previously legally accessioned into the permittee's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Trophy Applicants

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

Applicant: Steven Crews, Natchitoches, LA; Permit No. 15034D

Applicant: Milton Schultz, Glen Rose, TX; Permit No. PER0052836

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to regulations.gov and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2022–21144 Filed 9–28–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWRO–TUSK–34140; PPPWTUSK00, PPMPSPD1Z.YM0000]

Tule Springs Fossil Beds National Monument Advisory Council Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Park Service is hereby giving notice that the Tule Springs Fossil Beds

National Monument Advisory Council (Council) will meet as indicated below.

DATES: The meeting will be held on Wednesday, November 16, 2022, at 5:00 p.m. until 7:00 p.m. (PACIFIC).

ADDRESSES: The meeting will be held in person at the State Park Nevada—Southern Nevada Office at 4747 Vegas Dr., Las Vegas, Nevada 89108. Individuals that prefer to participate virtually must contact the person listed in the (**FOR FURTHER INFORMATION CONTACT**) section at least five (5) business days prior to the meeting. The format and/or location of the meeting are subject to change depending on local health restrictions or mandates.

Written comments can be submitted by mail to Jeff Axel, Acting Superintendent, Tule Springs Fossil Beds National Monument, 601 Nevada Way, Boulder City, NV 89005, or by email *jeff_axel@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from Christa Johnston, Public Affairs Officer, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, Nevada 89005, via telephone at (702) 293–8691, or email at *christa_johnston@nps.gov.* 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: The Council was established pursuant to section 3092(a)(6) of Public Law 113–291 and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The purpose of the Council is to advise the Secretary of the Interior with respect to the preparation and implementation of the management plan.

Purpose of the Meeting: The Council agenda will include:

1. Minutes Review
2. Superintendent Updates will include:
   General Management Plan—Update of Civic Engagement & Stakeholder Meetings for General Management Plan
3. Resource Management Updates
4. Old Business
5. New Business
6. Public Comments

The meeting is open to the public. Interested persons may make oral or written presentations to the Council during the business meeting or file written statements. Requests to address the Council should be made to the Superintendent prior to the meeting. Members of the public may submit written comments by mailing them to Jeff Axel, Acting Superintendent, Tule Springs Fossil Beds National Monument, 601 Nevada Way, Boulder City, NV 89005, or by email *jeff_axel@nps.gov.* All written comments will be provided to members of the Council. Due to time constraints during the meeting, the Council is not able to read written public comments submitted into the record. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited.

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: 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.

Authority: 5 U.S.C. appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022–21055 Filed 9–28–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKRO–DENA–34487; PPAKAKROR4] [PPMPRLE1Y.LS0000]

National Park Service Alaska Region Subsistence Resource Commission Program; Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice the Denali National Park Subsistence Resource Commission (SRC) will meet as indicated below.

DATES: The Denali National Park SRC will meet via teleconference from 6:30 p.m. to 8:30 p.m. or until business is completed on Tuesday, November 8, 2022. The alternate meeting date is Thursday, November 10, 2022, from 6:30 p.m. to 8:30 p.m. or until business is completed at the same location. Teleconference participants must call (866) 810–1272 and use participant code 5366629.

FOR FURTHER INFORMATION CONTACT: For more detailed information regarding these meetings, or if you are interested in applying for SRC membership, contact Designated Federal Official Brooke Merrell, Superintendent, at (907) 683–9627, or via email at *brooke_merrell@nps.gov* or Amy Craver, Subsistence Coordinator, at (907) 644–3604 or via email at *amy_craver@nps.gov* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *kim_jochum@nps.gov.* 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: The NPS is holding meetings pursuant to the Federal Advisory Committee Act (5 U.S.C. appendix 1–16). The NPS SRC program is authorized under title VIII, section 808 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3118).

SRC meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded, and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting.

Purpose of the Meeting: The agenda may change to accommodate SRC business. The proposed meeting agenda includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introduction
3. Review and Adoption of Agenda
4. Superintendent's Welcome and Review of the SRC Purpose
5. Old Business—resume work not finished at the August 24, 2022, meeting

6. New Business—Review of Individual Customary and Traditional Use Determination requests.
7. Public and Other Agency Comments
8. Set Tentative Date and Location for Next SRC Meeting
9. Adjourn Meeting

SRC meeting location and date may change based on inclement weather or exceptional circumstances, including public health advisories or mandates. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and/or radio stations to announce the rescheduled meeting. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the (see **FOR FURTHER INFORMATION CONTACT**) section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: 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.

Authority: 5 U.S.C. appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022–21057 Filed 9–28–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–34399; PPNEGATEB0, PPMVSCS1Z.Y00000]

Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee (Committee) will meet as indicated below.

DATES: The virtual meeting will take place on Wednesday, October 19, 2022. The meeting will begin at 9:00 a.m. until 1:00 p.m., with a public comment period at 11:00 a.m. to 11:30 p.m. (EASTERN), with advance registration required. Individuals that wish to participate must contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than October 17, 2022, to receive instructions for accessing the meeting. The alternate meeting date is Thursday, November 3, 2022.

FOR FURTHER INFORMATION CONTACT: This will be a virtual meeting. Anyone interested in attending should contact Daphne Yun, Acting Public Affairs Officer, Gateway National Recreation Area, 210 New York Avenue, Staten Island, New York 10305, by telephone (718) 815–3651, or by email *daphne_yun@nps.gov.* 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: The Committee was established on April 18, 2012, by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906 and is regulated by the Federal Advisory Committee Act. The Committee provides advice to the Secretary, through the Director of the NPS, on matters relating to the Fort Hancock Historic District of Gateway National Recreation Area. All meetings are open to the public.

Purpose of the Meeting: The Gateway National Recreation Area will discuss the leasing program, working group updates, Stillman update, and various park updates. The final agenda will be posted on the Committee's website at *https://www.forthancock21.org.* The website includes meeting minutes from all prior meetings.

Interested persons may present, either orally or through written comments, information for the Committee to consider during the public meeting. Written comments will be accepted prior to, during, or after the meeting. Members of the public may submit written comments by mailing them to the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record. Individuals or groups requesting to make oral comments at the public Committee meeting will be limited to no more than three minutes per speaker. All comments will be made part of the public record and will be electronically distributed to all Committee members. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your written comments, you should be aware that your entire comment including your personal identifying information will be publicly available. 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.

(Authority: 5 U.S.C. appendix 2)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022–21056 Filed 9–28–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On September 22, 2022, the Department of Justice lodged a proposed consent decree with the United States District Court for the Southern District of Ohio in the lawsuit entitled *United States* v. *ALTIVIA Petrochemicals, LLC,* Civil Action No. 1:21-cv-00640.

The proposed Consent Decree will resolve an action filed in October 2021 relating to emissions of hazardous air pollutants from ALTIVIA's petrochemical manufacturing facility located in Haverhill, Ohio in violation of section 113(a)(3) of the Clean Air Act (CAA), 42 U.S.C. 7413(a)(3). The United States alleged violations of the National Emissions Standards for Organic Hazardous Air Pollutants (NESHAP) for

the Synthetic Organic Chemical Manufacturing Industry (SOCMI), 40 CFR part 63, subparts F, G, and H (''Hazardous Organic NESHAP'' or HON), and ALTIVIA's title V permit. These violations relate to ALTIVIA's significant failure to comply with leak detection and repair (LDAR) obligations under the HON, including thousands of missed monitoring events of valves and connectors, as well as a general failure to monitor valves in accordance with EPA Reference Method 21. Under the proposed Consent Decree, ALTIVIA will control emissions from Unit 202–F, implement a five-year Enhanced LDAR Program with three independent audits, and pay a $1,112,500 civil penalty.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *ALTIVIA Petrochemicals, LLC,* D.J. Ref. No. 90–5–2–1–11905. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $18.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–21100 Filed 9–28–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before October 31, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2022–050 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2022–050.
2. *Fax:* 202–693–9441.
3. *Email: petitioncomments@dol.gov.*
4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, *Attention:* S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2022–019–C.

Petitioner: Signal Peak Energy, LLC, 100 Portal Drive, Roundup, Montana 59072.

Mine: Bull Mountains Mine No. 1, MSHA ID No. 24–01950, located in Musselshell County, Montana.

Regulation Affected: 30 CFR 18.35(a)(5)(i), Portable (trailing) cables and cords.

Modification Request: The petitioner requests a modification of 30 CFR 18.35(a)(5)(i) to permit 1,000-foot versus the specified 700-foot No. 2 American Wire Gauge (AWG) 995-volt trailing cables for shuttlecars and roof bolters and to permit 1,000-foot versus the 850-foot ⅔ 995-volt trailing cables for continuous mining machines.

The petitioner states that:

(a) The implementation of up to 1,000-foot trailing cables will eliminate the need for distribution boxes and their associated hazards, currently necessary to develop Bull Mountain Mine No. 1 pillar sizes in continuous mining sections.

(b) Minimizing the need for distribution boxes in continuous mining sections will reduce redundant electrical connections, reduce exposure to hazards related to setting breakers, and remove an installation that is prone to damage from passing equipment.

(c) The Bull Mountains Mine No. 1 runs continuous mining sections with two shuttlecars, one or two roof bolters, and two continuous mining machines.

(d) Cuts are made on 40-foot increments. Pillar dimensions are approved on centers up to 250 feet. Large block sizes are implemented for pillar stability, abutment control, and prevent ventilation pressure loss.

(e) The use of distribution boxes is currently necessary in areas where large pillar sizes are implemented. This includes Startlines, Recovery Rooms, and applications in Mains development.

(f) To comply with maximum trailing cable lengths, distribution boxes must be installed and advanced every crosscut in areas with pillar centers

(240-foot × 184-foot and 222-foot × 90-foot).

(g) Distribution boxes are redundant pieces of electrical equipment that must be handled and advanced every crosscut, progressively, to achieve the same results as a 1,000-foot trailing cable.

The petitioner proposes the following alternative method:

(a) The maximum length of 995-volt trailing cables will be 1,000 feet. The size of 995-volt trailing cables will be:

(1) no smaller than 2/0 for continuous mining machines;

(2) no smaller than No. 2 AWG for roof bolters and shuttlecars.

(b) All circuit breakers used to protect 2 AWG trailing cables exceeding 700 feet in length or 2/0 cables exceeding 850 feet in length shall have circuit breakers properly calibrated and adjusted to trip at no more than the smallest of the following values:

(1) The setting specified in 30 CFR 75.601–1,

(2) The setting specified in the approval documentation for the machine, or

(3) 70 percent of the minimum phase to phase short-circuit current available at the end of the trailing cable.

(c) Cable size and maximum allowable circuit breaker instantaneous settings will be labeled at the breaker. In addition, permanent warning labels will be installed and maintained warning miners not to change or alter the short-circuit settings.

(d) Prior to each production shift, persons designated by the operator will visually examine trailing cables to ensure that the cables are in safe operating condition and that the instantaneous settings of calibrated circuit breakers are compliant with labeled settings.

(e) Any trailing cable that is not in safe operating condition shall be removed from service immediately and repaired or replaced.

(f) Each splice or repair to the trailing cables shall be made in a workmanlike manner and in accordance with the instructions of the manufacturer of the splice repair kit. Splices will be made with an MSHA-approved splice wrap.

(g) The petitioner's alternative method will not be implemented until all miners who have been designated to examine trailing cables and verify instantaneous settings have received all the elements of necessary training.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–21095 Filed 9–28–22; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before October 31, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2022–051 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments for MSHA–2022–051.
2. *Fax:* 202–693–9441.
3. *Email: petitioncomments@dol.gov*.
4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, *Attention:* S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2022–020–C.

Petitioner: UC Mining, LLC, 835 State Route 1179, Waverly, Kentucky, 42462.

Mine: UC Mining, LLC Mine, MSHA ID No. 15–02709, located in Union County, Kentucky.

Regulation Affected: 30 CFR 77.1914 (a), Electrical equipment.

Modification Request: The petitioner requests a modification of 30 CFR 77.1914 (a) to permit using a non-permissible brake car on the slope hoist to transport men and materials in and out of the slope, inby the collar during the excavation of the 11 seam turnout in the mine slope.

The petitioner states that:

(a) Miners will be better protected from hoist overspeed and rope breakage by using a brake car for transportation in and out of the slope.

(b) Miners will also be better protected by riding in a covered car versus an open car.

The petitioner proposes the following alternative method:

(a) The battery-powered Frontier Kemper/Lake Shore Sanford-Day Brakeman Car, serial number BC–163–19, model number BSD–2–42 will be operated in intake air at all times.

(b) The intake air in the slope will remain below 1 percent methane at all times.

(c) If the methane level approaches or reaches 1 percent, all power including the battery-powered Brakeman Car shall be removed and corrections to the ventilation system shall be made.

(d) Tests for methane shall be conducted within the slope as required by the standard.

(e) The Brakeman car shall be equipped with onboard communication and an emergency stop feature.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–21096 Filed 9–28–22; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before October 31, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2022–0048 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments for MSHA–2022–0048.
2. *Fax:* 202–693–9441.
3. *Email: petitioncomments@dol.gov*.
4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, *Attention:* S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2022–018–C.

Petitioner: Buchanan Minerals, LLC, Company, PO Drawer L, Oakwood VA 24631.

Mine: Buchanan No. 1 Mine, MSHA ID No. 44–04856 located in Buchanan County, Virginia.

Regulation Affected: 30 CFR 75.1100–2 (b), Quantity and location of firefighting equipment.

Modification Request: The petitioner requests a modification of 30 CFR 75.1100–2 (b) to allow an alternative to the installation of a parallel waterline along the entire length of the belt conveyor that will be utilized in the development of three-entry longwall headgate and subsequent longwall retreat sections. The petitioner proposes installing the waterline in the adjacent entry to the belt conveyor and extending the distance between fire hydrants to 320 feet on three-entry longwall headgate development and subsequent longwall retreat sections.

The petitioner states that:

(a) Currently, as numbered left to right, No.1 entry serves as the return, No. 2 entry serves as the intake/track entry, and No. 3 entry serves as the belt entry.

(b) The headings are on 160-foot centers and the crosscuts from the No.2 Entry to the No.3 Entry are on 60-foot centers. The No. 2 intake/track entry is isolated from the No. 3 belt entry by permanent cement block stoppings. The mine seam heights are 48 inches or higher. In accordance with 30 CFR 75.333 (c) (1), personnel doors are installed at distances not to exceed 600 feet.

(c) A 6-inch waterline is installed along the full length of the track.

(d) The following two methods are utilized to facilitate the requirements of 30 CFR 75.1100–2 (b):

(1) A 2-inch waterline is installed along the belt conveyor with fire valves installed at intervals of 300 feet.

(2) The 2-inch waterline is supplied via the 6-inch line through taps at intervals necessary to ensure flow rate requirements are met; or a 2-inch waterline is branched off the 6-inch waterline at every break and extended over to the No. 3 belt entry with a corresponding fire valve fitted on the end of each branch.

(e) The new gateroad design will utilize 1,000-foot-wide longwall faces and require crosscuts to be driven on 160-foot centers. This crosscut spacing is critical to the global stability of the mine environment. The design was reviewed by MSHA's Technical Support Roof Control Group which found it to have merit.

(f) The petitioner is applying to reconfigure the 6-inch waterline in the adjacent entry to the belt conveyor and extend the distance between fire hydrants from 300 feet to 320 feet on three-entry longwall headgate development and subsequent longwall retreat sections. The waterline will be located in the No. 2 intake/track entry with the exception of a final connection that will extend the waterline to the section loading point in the No. 3 belt entry. Additional fire-fighting equipment will be staged and enhanced access between the No. 2 and No. 3 entry will be instituted. The utilization of the waterline in the No. 2 intake/track entry will facilitate both the installation of the waterline during development and removal upon longwall retreat mining.

(g) Should an issue arise affecting the water delivery system, the problem can be readily identified due to the waterline's location along the track that is more frequently traveled than the belt entry.

(h) With the waterline located in the No. 2 intake/track entry as compared to the No. 3 belt entry, it is less likely to be compromised due to fire and extreme heat exposure resulting in pressure loss.

(i) The alternative waterline installation will require less material handling thus reducing the risk of injury, especially hand and back-related injuries.

(j) The additional fire hose, fire hose nozzles, and three-way manifold will

provide enough firefighting capability to adequately charge two fire-fighting hoses that can reach the corresponding break of the next fire valve location.

(k) The delivery of individuals and firefighting materials is simplified and expedited by the utilization of the track. This, in conjunction with the readily available and easily identifiable fire valves, will lessen the response time to contain and extinguish a fire.

(l) To simplify training, the fire valve location can be explained as located in every other break along the track entry.

(m) The initial steps of hooking up the fire-fighting equipment to the fire valve will take place in the isolated intake escapeway.

(n) For command-and-control purposes, communication and tracking systems are optimal in the No. 2 intake/track entry.

The petitioner proposes the following alternative method:

(a) The 6-inch waterline shall be installed in an entry adjacent to the conveyor belt entry with the fire hydrants located at the crosscuts connecting the intake/track entry and the belt entry. The 6-inch waterline will be located along the rib line nearest to the No. 3 belt entry.

(b) The fire hydrants shall be spaced not more than 320 feet apart.

(c) The fire hydrants shall be operable, clearly identified, and positioned such that the hose can be quickly connected to the outlet in the event of an emergency.

(d) Access to the fire hydrants shall be maintained clear of obstructions.

(e) Signs shall be conspicuously placed in the belt entry indicating the location of each fire hydrant.

(f) Between the No. 2 intake/track entry and the No. 3 belt entry, personnel doors shall be installed at distances not to exceed 320 feet and maintained in operable condition in the stopping opposite each fire hydrant to allow easy access to the hydrant.

(g) In addition to the 500 feet of fire hose required by 30 CFR 75.1100–2 (b), at least 300 feet of extra fire hose shall be kept in the immediate area of the section belt drive. The strategically located fire hose shall be sufficient in length so that any affected area on the belt can be covered from the most proximate fire hose outlet. Two fire hose nozzles and a three-way manifold shall be provided in the fire hose cache.

(h) A fire valve shall be installed at the section tailpiece and will be supplied by a suitably sized and rated water hose extending from the 6-inch waterline. If required, additional fire valves shall be installed in the suitably sized and rated water hose between the 6-inch waterline and section tailpiece to maintain the 320-foot interval. The fire valves shall be capable of delivering a minimum of 50 gallons of water a minute at a nozzle pressure of 50 pounds per square inch.

(i) Prior to implementing the Proposed Decision and Order, all persons who inspect, install, and maintain the waterline shall be instructed in the special terms and conditions of this alternative method. Within 60 days after the Proposed Decision and Order becomes final, the petitioner shall submit proposed revisions for their approved 30 CFR part 48 training plan to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the alternative method outlined in the Proposed Decision and Order and the special terms and conditions stated in the Proposed Decision and Order.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–21094 Filed 9–28–22; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collections, Supervisory Committee Audits and Verifications

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following extension of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before November 28, 2022 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, Virginia 22314; email at *PRAComments@NCUA.gov. Given the limited in-house staff because of the COVID–19 pandemic, email comments are preferred.*

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Dawn Wolfgang at the address above or telephone 703–548–2279.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0059.

Title: Supervisory Committee Audits and Verifications, 12 CFR 715.

Type of Review: Extension of a currently approved collection.

Abstract: Title 12 CFR part 715 prescribes the responsibilities of the supervisory committee to obtain an audit of the credit union and verification of member accounts as outlined in section 115 of the Federal Credit Union Act, 12 U.S.C. 1761d. A supervisory committee audit is required at least once every calendar year covering the period since the last audit and to conduct a verification of members' accounts not less frequently than once every two years. The information is used by both the credit union and the NCUA to ensure through audit testing that the credit union's assets, liabilities, equity, income, and expenses exist, are properly valued, controlled and meet ownership, disclosure and classification requirements of sound financial reporting.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,308.

Estimated No. of Responses per Respondent: 4.16.

Estimated Total Annual Responses: 22,086.

Estimated Burden Hours per Response: 0.57.

Estimated Total Annual Burden Hours: 12,549.

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 execution 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 Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on September 23, 2022.

Dated: September 26, 2022.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2022–21105 Filed 9–28–22; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Subject 60-Day Notice for the "Shakespeare in American Communities/Juvenile Justice: Data Collection Forms" Proposed Collection; Comment Request

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the NEA is soliciting comments concerning the proposed information collection for Shakespeare in American Communities/Juvenile Justice subgrantees, which will include a survey for teaching artists, and supplemental application and final report forms. Copies of the current information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**.

ADDRESSES: Send comments to Sunil Iyengar, National Endowment for the Arts, via email (*research@arts.gov*).

SUPPLEMENTARY INFORMATION: The NEA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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 submissions of responses.

Dated: September 26, 2022.

Bonita Smith,

Director, Office of Administrative Services & Contracts, National Endowment for the Arts.

[FR Doc. 2022–21110 Filed 9–28–22; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Mathematical and Physical Sciences (#66).

Date and Time:

October 25, 2022: 10:05 a.m. to 5:00 p.m.

October 26, 2022: 8:30 a.m. to 3:05 p.m.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314.

Hybrid participation for AC Members and Presenters. Other visitors and guests will be able to virtually attend the meeting.

To attend the virtual meeting, please send your request for the virtual meeting link to Michelle Bushey at the following email address: *mbushey@nsf.gov.*

Type of Meeting: Open.

Contact Person: Rachel Abraham, National Science Foundation, 2415 Eisenhower Avenue, Room C 9000, Alexandria, Virginia 22314; Telephone: 703/292–4659.

Meeting Information: http://www.nsf.gov/mps/advisory.jsp.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to MPS programs and activities.

Agenda

Tuesday, October 25, 2022

- Call to Order and Official Opening of the Meeting
- Approval of Prior Meeting Minutes—MPSAC Chair
- MPS Update by Assistant Director
- Science Highlight
- GRANTED
- Articulating Impacts of Basic Research
- Facilities Status Update
- Preparation for discussion with NSF Director, Chief Operating Officer, Chief of Staff
- Closing remarks and adjourn day 1

Wednesday, October 26, 2022

- Welcome and overview of agenda
- Science Highlight
- Waterman Canvassing Group
- Environmental Research and Education (ERE) AC followup
- Quantum Information Science
- Climate Change and Clean Energy
- Preparation for discussion with NSF Director, Chief Operating Officer, Chief of Staff
- Meeting and discussion with NSF Director, Chief Operating Officer, Chief of Staff
- Closing remarks and adjourn

Dated: September 26, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–21164 Filed 9–28–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–7513; NRC–2021–0193]

Kairos Power, LLC; Hermes Test Reactor

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft environmental impact statement; request for comment and public comment meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft NUREG–2263, Environmental Impact Statement (EIS) for the Construction Permit for the Kairos Hermes Test Reactor. Kairos Power, LLC (Kairos) is requesting a license to construct a test reactor in Oak Ridge, Tennessee. The NRC is seeking public comment on this action and has scheduled a public meeting that will

take place both in Oak Ridge, Tennessee and as an online webinar.

DATES: Submit comments by December 6, 2022. 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. On November 16, 2022, the NRC is planning to hold a public meeting and an online webinar, to present an overview of its preliminary analysis and to receive comments from 7:00 p.m. until 9:00 p.m. Eastern Time (ET), See Section IV, ''Request for Comment and Public Meeting,'' of this notice for additional information.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Email comments to: KairosHermes-CPEIS@nrc.gov.*
- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0193. Address questions about Docket IDs in *Regulations.gov* 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.

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: Tamsen Dozier, telephone: 301–415–2272, email: *Tamsen.Dozier@nrc.gov,* or Peyton Doub, telephone: 301–415–6703, email: *Peyton.Doub@nrc.gov.* Both are staff members of the Office of Nuclear Material Safety and Safeguards at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0193 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0193.
- *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, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The draft EIS is available in ADAMS under Accession No. ML22259A126.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. 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 8:00 a.m. and 4:00 p.m. ET, Monday through Friday, except Federal holidays.
- *Project Website:* Information related to the Hermes—Kairos project can be accessed on the NRC's website at: *https://www.nrc.gov/reactors/non-power/hermes-kairos.html.*
- *Public Library:* A copy of the draft EIS will be available at the Oak Ridge Public Library, 1401 Oak Ridge Turnpike, Oak Ridge, Tennessee 37830.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0193 in 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.

Comments submitted through the NRC project email address will be processed into ADAMS, and all comments will be compiled and addressed in the final EIS.

II. Background

By letter dated November 29, 2021 (ADAMS Accession No. ML21319A354) the NRC staff informed Kairos of its determination that the Kairos application for a construction permit for the Hermes test reactor was acceptable for docketing under Docket No. 50–7513. A notice of acceptance for docketing of the application was published in the **Federal Register** on December 1, 2021 (86 FR 68290) and a notice of opportunity for hearing was published on February 9, 2022 (87 FR 7503). A notice of intent to prepare an environmental impact statement and to conduct scoping process was published in the **Federal Register** on February 18, 2022 (87 FR 9394).

III. Discussion

As set forth in Section 51.20(b)(1) of title 10 of the *Code of Federal Regulations* (10 CFR), issuance of a construction permit (CP) under 10 CFR part 50 for a testing facility is an action that requires an EIS. This notice is being published in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the NRC's regulations in 10 CFR part 51. In addition, as outlined in 36 CFR 800.8(c), ''Coordination with the National Environmental Policy Act,'' the NRC staff has been coordinating compliance with Section 106 of the National Historic Preservation Act (NHPA) with steps taken to meet the requirements of NEPA. Pursuant to 36 CFR 800.8(c), the NRC staff used the process and documentation for the preparation of the draft EIS on the proposed action to comply with Section 106 of the NHPA in lieu of the procedures set forth in 36 CFR 800.3 through 800.6.

The draft EIS includes the NRC staff's preliminary analysis of the environmental impacts of the proposed action of deciding whether to issue a construction permit to Kairos. After weighing the environmental, economic, technical, and other benefits against environmental and other costs, the NRC staff's preliminary recommendation, unless safety issues mandate otherwise, is that the operating license be issued as requested.

IV. Request for Comment and Public Meeting

The NRC staff is requesting public comment on the draft EIS for the Construction Permit for the Kairos Hermes Test Reactor. On November 16, 2022, the NRC is planning to hold a public meeting and an online webinar, to present an overview of its preliminary analysis and to receive comments from 7:00 p.m. until 9:00 p.m. ET, at the Hilton DoubleTree at 215 S Illinois Avenue in Oak Ridge, Tennessee. A court reporter will transcribe all comments received during the public meeting and the transcript will be made publicly available. To be considered, comments must be provided either at the transcribed public meeting or in writing, as discussed in the **ADDRESSES** section of this document.

Additionally, the NRC staff will host an informal discussion at the Hilton DoubleTree for 1 hour prior to the start of the meeting for those attending the meeting in person. No formal comments will be accepted during the informal discussions.

Persons interested in attending this public meeting should monitor the NRC's Public Meeting Schedule website at *https://www.nrc.gov/pmns/mtg* for additional information, agendas for the meeting, and access information. Meeting details will also be available by November 1, 2022 at *https://www.nrc.gov/reactors/non-power/hermes-kairos.html.* Those wishing to speak and voice comments at the public meeting should follow the instructions listed on the NRC's Public Meeting Schedule website. The NRC encourages those wishing to voice comments during the meeting to register in advance by sending an email to *KairosHermes-CPEIS@nrc.gov* and indicate if attending in-person or remotely. Please contact Tamsen Dozier no later than November 1, 2022, if accommodations or special equipment is needed to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated.

Dated: September 26, 2022.

For the Nuclear Regulatory Commission.

Kenneth T. Erwin,

Chief, Environmental Review New Reactors Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–21125 Filed 9–28–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–137 and CP2022–141; MC2022–138 and CP2022–142; MC2022–139 and CP2022–143; MC2022–140 and CP2022–144]

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:* October 3, 2022.

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).:* MC2022–137 and CP2022–141; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 48 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 23, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 3, 2022.

2. *Docket No(s).:* MC2022–138 and CP2022–142; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 49 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 23, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 3, 2022.

3. *Docket No(s).:* MC2022–139 and CP2022–143; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 50 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 23, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* October 3, 2022.

4. *Docket No(s).:* MC2022–140 and CP2022–144; *Filing Title:* USPS Request

[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).

to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 51 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 23, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* October 3, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–21124 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 23, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 48 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–137, CP2022–141.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21079 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 20, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 40 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–127, CP2022–131.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21061 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 34 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–121, CP2022–125.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21052 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 21, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 42 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–130, CP2022–134.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21072 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel*

Select Service Contract 33 to Competitive Product List. Documents are available at *www.prc.gov,* Docket Nos. MC2022–120, CP2022–124.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21051 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 35 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–122, CP2022–126.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21053 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 37 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–124, CP2022–128.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21059 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 47 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–136, CP2022–140.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21078 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service®.

ACTION: Notice of modified systems of records.

SUMMARY: The United States Postal Service® (Postal Service) is proposing to revise a Customer Privacy Act System of Records (SOR). These modifications are being made to support an initiative to identify population mobility trends in the aggregate.

DATES: These revisions will become effective without further notice on October 31, 2022, unless in response to comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be submitted via email to the Privacy and Records Management Office, United States Postal Service Headquarters (*privacy@usps.gov*). To facilitate public inspection, arrangements to view copies of any written comments received will be made upon request.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy and Records Management Officer, Privacy and Records Management Office, 202–268–3069 or *privacy@usps.gov*.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service has determined that Customer Privacy Act System of Records, USPS 800.000 Address Change, Mail Forwarding, and Related Services should be revised

I. Background

The Postal Service is proposing to utilize ZIP Code™ data from the National Change-of-Address (COA) system to identify household population mobility trends.

The Postal Service will limit the trend analysis to ZIP Code data extracted (or taken) from old and new address location information submitted by customers filing COA requests.

The numerical ZIP Code data will be used in aggregate to determine household population movement and mobility trends within the United States.

Information will be restricted to ZIP Code data only, provided by customers that have submitted COA requests. No Personally Identifiable Information (PII) will be associated with ZIP Code data used for analyzing and determining population mobility trends. No PII will be retained or utilized to conduct the proposed household population mobility trend analysis.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The Postal Service is proposing to modify SOR 800.000 Address Change, Mail Forwarding, and Related Services, to identify population mobility trends in the aggregate.

A new purpose is being added to the existing SOR, appearing as purpose number 12.

III. Description of the Modified System of Records

Pursuant to 5 U.S.C. 552a (e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed revisions has been sent to Congress and to the Office of Management and Budget for their evaluations. The Postal Service does not expect this amended system of records to have any adverse effect on individual privacy rights. The notice for USPS SOR 800.000, Address Change, Mail Forwarding, and Related Services.is provided below in its entirety, as follows:

SYSTEM NAME AND NUMBER:

USPS 800.000, Address Change, Mail Forwarding, and Related Services.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

USPS National Customer Support Center (NCSC), Computerized Forwarding System (CFS) sites, Post Offices, USPS Processing and Distribution Centers, USPS IT Eagan Host Computing Services Center, and contractor sites.

SYSTEM MANAGER(S):

Vice President, Enterprise Analytics, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–5626, (202) 268–7542.

Vice President, Delivery Operations, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–7116, (202) 268–6500.

Vice President, Customer Experience, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–0004, (202) 268–2252.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

39 U.S.C. 401(2), 403, and 404(a)(1).

PURPOSE(S) OF THE SYSTEM:

1. To provide mail forwarding and Change of Address (COA) services, including local community information, and move related advertisements.

2. To provide address correction services.

3. To counter efforts to abuse the COA process.

4. To provide address information to the American Red Cross or other disaster relief organization about a customer who has been relocated because of disaster.

5. To support investigations related to law enforcement for fraudulent transactions.

6. To provide automatic updates to USPS customer systems using mail forwarding and COA services.

7. To facilitate communication between USPS customers and the Postal Service with regard to COA and address correction services.

8. To enhance the customer experience by improving the security of COA and Hold Mail processes.

9. To protect USPS customers from becoming potential victims of mail fraud and identity theft.

10. To identify and mitigate potential fraud in the COA and Hold Mail processes.

11. To verify a customer's identity when applying for COA and Hold Mail services.

12. To provide input into aggregate household population mobility trend analysis using numerical ZIP Code location data from Change-of-Address (COA) requests.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Customers requesting Change of Address (COA), mail forwarding, or other related services either electronically or in writing.

Customers who are victims of a natural disaster who request mail forwarding services through the Postal Service or the American Red Cross.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. Customer information: Name, title, signature, customer number, old address, new address, filing date, email address(es), telephone numbers, and other contact information.

2. Verification and payment information: Credit and/or debit card number, type, and expiration date; or date of birth and driver's state and license number; information for identity verification; and billing information. Customers who are victims of a natural disaster who request mail forwarding service electronically may be required to provide date of birth for verification if credit and/or debit card information is unavailable.

3. Demographic information: Designation as individual/family/business.

4. Customer preferences: Permanent or temporary move; mail forwarding instructions; service requests and responses.

5. Customer inquiries and comments: Description of service requests and responses.

6. Records from service providers for identity verification.

7. Online user information: internet Protocol (IP) address, domain name, operating system versions, browser version, date and time of connection, and geographic location.

8. Protective Court Orders filed with change-of-address and mail forwarding requests for individuals, also referred to as Court Ordered Protected Individuals (COPI).

RECORD SOURCE CATEGORIES:

Customers, personnel, contractors, service providers, and for call center operations, commercially available sources of names, addresses, and telephone numbers. For emergency change-of-addresses only, commercially available sources of names, previous addresses, and dates of birth. For alternative authentication, sources of names, previous and new addresses, dates of birth, and driver's state and license number.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Standard routine uses 1. through 7., 10., and 11. apply. In addition:

a. Disclosure upon request. The new address of a specific business or organization that has filed a permanent change-of-address order may be furnished to any individual on request. (Note: The new address of an individual or family will not be furnished pursuant to this routine use, unless authorized by one of the standard routine uses listed above or one of the specific routine uses listed below.) If a domestic violence shelter has filed a letter on official letterhead from a domestic violence coalition stating (i) that such domestic violence coalition meets the requirements of 42 U.S.C. 10410 and (ii) that the organization filing the change of address is a domestic violence shelter, the new address shall not be released except pursuant to routine use d, e, or f pursuant to the order of a court of competent jurisdiction.

b. Disclosure for Address Correction. Disclosure of any customer's new permanent address may be made to a mailer, only if the mailer is in possession of the name and old address: From the National Change-of-Address Linkage (NCOALink®) file if the mailer is seeking corrected addresses for a mailing list; from the Computerized Forwarding System (CFS), from the Postal Automated Redirection System (PARS) if a mailpiece is undeliverable

as addressed, or from the Locatable Address Conversion System if an address designation has been changed or assigned. Copies of change-of-address orders may not be furnished. In the event of a disaster or manmade hazard, temporary address changes may be disclosed to a mailer when, in the sole determination of the Postal Service, such disclosure serves the primary interest of the customer, for example, to enable a mailer to send medicines directly to the customer's temporary address, and only if the mailer is in possession of the customer's name and permanent address. If a domestic violence shelter has filed a letter on official letterhead from a domestic violence coalition stating (i) that such domestic violence coalition meets the requirements of 42 U.S.C. 10410 and (ii) that the organization filing the change of address is a domestic violence shelter, the new address shall not be released except pursuant to routine use d, e, or f pursuant to the order of a court of competent jurisdiction.

c. Disclosure for Voter Registration. Any customer's permanent change of address may be disclosed to a duly formed election board or registration commission using permanent voter registration. Copies of change of address orders may be furnished.

d. Disclosure to Government Agency. Any customer's permanent or temporary change of address information may be disclosed to a federal, state, or local government agency upon prior written certification that the information is required for the performance of its duties. A copy of the change of address order may be furnished. Name and address information may be disclosed to government planning authorities, or firms under contract with those authorities, if an address designation has been changed or assigned.

e. Disclosure to Law Enforcement Agency. Any customer's permanent or temporary change of address information may be disclosed to a law enforcement agency, for oral requests made through the Postal Inspection Service, but only after the Postal Inspection Service has confirmed that the information is needed for a criminal investigation. A copy of the change of address order may be furnished.

f. Disclosure for Service of Process. Any customer's permanent or temporary change of address information may be disclosed to a person empowered by law to serve legal process, or the attorney for a party in whose behalf service will be made, or a party who is acting pro se, upon receipt of written information that meets prescribed certification requirements. Disclosure will be limited to the address of the specifically identified individual (not other family members or individuals whose names may also appear on the change of address order). A copy of the change of address order may not be furnished.

g. Disclosure for Jury Service. Any customer's change of address information may be disclosed to a jury commission or other court official, such as a judge or court clerk, for purpose of jury service. A copy of the change of address order may be furnished.

h. Disclosure at Customer's Request. If the customer elects, change of address information may be disclosed to government agencies or other entities.

i. Disclosure to a disaster relief organization. Any customer's permanent or temporary change of address may be disclosed to the American Red Cross or other disaster relief organizations, if that address has been impacted by disaster or manmade hazard.

All routine uses are subject to the following exception: Information concerning an individual who has filed an appropriate protective court order with the postmaster/CFS manager will not be disclosed under any routine use except pursuant to the order of a court of competent jurisdiction.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the following methods: For paper records: by name, address, date, and ZIP Code. For electronic records: by name, address, date, ZIP Code™, and customer number for electronic change of address and related service records; by name, address, and email address for customer service records.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

1. National change-of-address and mail forwarding records are retained 4 years from the effective date.

2. Delivery units access COA records from the Change-Of-Address Reporting System (COARS) database, which retains 2 years of information from the COA effective date. The physical change-of-address order is retained in the CFS unit for 30 days if it was scanned, or 18 months if it was manually entered into the national database.

3. Online user information may be retained for 12 months.

Records existing on paper are destroyed by shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records, computers, and computer storage media are located in controlled-access areas under supervision of program personnel. Access to these areas is limited to authorized personnel, who must be identified with a badge.

Access to records is limited to individuals whose official duties require such access. Contractors and licensees are subject to contract controls and unannounced on-site audits and inspections.

Computers are protected by mechanical locks, card key systems, or other physical access control methods. The use of computer systems is regulated with installed security software, computer logon identifications, and operating system controls including access controls, terminal and transaction logging, and file management software.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the Notification Procedure above and USPS Privacy Act.

CONTESTING RECORD PROCEDURES:

See NOTIFICATION PROCEDURES and RECORD ACCESS PROCEDURES.

NOTIFICATION PROCEDURES:

Customers wanting to know if information about them is maintained in this system of records should address inquiries to their local postmaster. Inquiries should contain full name, address, effective date of change order, route number (if known), and ZIP Code. Customers wanting to know if information about them is also maintained in the NCOA File should address such inquiries to: Manager, NCOA, National Customer Support Center, United States Postal Service, 225 N Humphreys Blvd. Ste 501, Memphis, TN 38188.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

December 27, 2018, 83 FR 66768; June 30, 2016, 81 FR 42760; August 21, 2014, 79 FR 49543; September 13, 2012, 77 FR 56676; July 17, 2008, 73 FR 41135; April 29, 2005, 70 FR 22516.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–21101 Filed 9–28–22; 8:45 am]

BILLING CODE P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 21, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 44 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–132, CP2022–136.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21062 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 23, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 49 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–138, CP2022–142.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21076 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Parcel Select Contract 52 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–133, CP2022–137.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21049 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 46 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–135, CP2022–139.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21070 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 36 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–123, CP2022–127.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21054 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a

domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 15, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 24 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–110, CP2022–114.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21048 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 21, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 79 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–129, CP2022–133.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21045 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 21, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 43 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–131, CP2022–135.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21074 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 23, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 51 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–140, CP2022–144.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21077 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 23, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 50 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–139, CP2022–143.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21075 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 20, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 41 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–128, CP2022–132.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21071 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 45 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–134, CP2022–138.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21064 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 20, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 39 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–126, CP2022–130.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–21060 Filed 9–28–22; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95899; File No. SR–MIAX–2022–30]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments

September 23, 2022.

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 September 13, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''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 Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Interpretation and Policy .03 to Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, 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 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

The Exchange proposes to amend Interpretation and Policy .03 to Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments, to change the minimum increment for all series of options on the SPIKES® Index[5] (''SPIKES options''). Currently, the minimum trading increment for SPIKES options is as follows: (1) if the options series is trading at less than $3.00, five (5) cents; and (2) if the options series is trading at $3.00 or higher, ten (10) cents.[6] The Exchange now proposes to amend Interpretation and Policy .03 to Exchange Rule 510 to change the minimum increment for SPIKES options to the following: (1) if the options series

[5] The SPIKES Index measures the expected 30-day volatility of the SPDR® S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY''). *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES® Index).

[6] *See* Exchange Rule 510, Interpretation and Policy .03.

is trading at less than $3.00, one (1) cent; and (2) if the options series is trading at $3.00 or higher, five (5) cents.

The Exchange believes market demand (including by retail investors, who generally prefer lower trading increments) supports a lower trading increment for these series. The Exchange expects this more granular pricing to lead to narrowing of the bid-ask spread for these options and increase the possible number of price points available to investors for these series. The Exchange believes tighter spreads will increase order flow in SPIKES options, which additional liquidity ultimately benefits all investors. Finer increments also permit more precise pricing in line with the theoretical value of these options. Additionally, penny pricing will be, but is not yet, available in options on the Cboe Volatility Index (''VIX options''), which is a competing product with SPIKES options trade [sic] on the Cboe Exchange, Inc. (''Cboe'').[7] The Exchange notes that the proposal to list VIX options in penny increments was noticed by the Commission on June 14, 2022, with the Commission granting waiver of the 30-day operative delay.[8] As a result, the Exchange believes penny pricing for SPIKES options is necessary for competitive reasons to allow the Exchange to price these options at the same level of granularity as permitted for competitor products.[9]

Further, the Exchange believes market demand supports a lower trading increment for series of SPIKES options, particularly demand by retail investors, who generally prefer lower trading increments. The Exchange is in the process of implementing a robust retail-oriented program for SPIKES options, including new educational programs and materials and potentially through changes to the MIAX Fee Schedule for transactions in SPIKES options, among other things. The proposed change to move to penny pricing for SPIKES options would further this goal by providing retail market participants the ability to trade SPIKES options in lower trading increments. The Exchange believes that lower trading increments in SPIKES options will boost retail participation on the Exchange, which should strengthen the market quality for SPIKES options for all market participants, leading to more trading opportunities and tighter spreads.

With regard to the impact of this proposed rule change on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority have the necessary systems capacity to handle any potential additional traffic associated with this proposal. The Exchange does not believe any potential increased traffic will become unmanageable since this proposed rule change with respect to minimum trading increments is limited to a single class of options. The proposed rule change does not impact the number of expirations or strike prices for SPIKES options the Exchange may list pursuant to Exchange Rule 1809(a)(3).

The Exchange will issue a notice to Members [10] via Regulatory Circular with appropriate advanced notice announcing the implementation date of the proposed rule change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to prevent fraudulent and manipulative 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change will permit more granular pricing in SPIKES options, which may lead to narrowing of the bid-ask spread for these options and increase the possible number of price points available to investors for these series, which ultimately increases liquidity to the benefit of all investors. In particular, the Exchange believes the proposed change will further the Exchange's goal of providing retail market participants the ability to trade SPIKES options in lower trading increments, which will strengthen the market quality for SPIKES options for all market participants, leading to more trading opportunities and tighter spreads. The Exchange believes stronger market quality and more trading opportunities based on a lower trading increment for SPIKES options promotes just and equitable principles of trade, facilitates transactions in SPIKES options and removes impediments to the mechanism of a free and open market for SPIKES options.

Additionally, as discussed above, at least one competing exchange, Cboe, has filed to allow a competitive product, VIX options, to trade in penny and nickel increments once Cboe implements that change. Therefore, the proposed change will and promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market by allowing SPIKES options to trade at the same level of granularity as permitted for competitor products like VIX options. Further, the Commission has previously allowed singly-listed options to be quoted in penny increments when such options were designed to track the same indexes as multiply-listed options that were in the pilot version (at the time) of the Penny Interval Program.[14]

[7] *See* Securities Exchange Act Release No. 95102 (June 14, 2022), 87 FR 36898 (June 21, 2022) (SR–CBOE–2022–027) (proposal to amend the minimum price increment for VIX options not listed under the Nonstandard Expirations Pilot Program to be $0.01 for series trading lower than $3.00 and $0.05 for series trading at $3.00 or higher) (the ''VIX Options Penny Notice''). The Exchange notes that series of VIX options listed under the Nonstandard Expirations Pilot Program (''VIXW options'') currently trade with a minimum increment of $0.01 for all series trading prices. *See* Cboe Exchange, Inc. Rule 5.4(a).

[8] *See id.* The Exchange notes that Cboe stated in their rule filing that Cboe ''will issue a Notice to Trading Permit Holders . . . with appropriate advanced notice announcing the implementation date of the proposed rule change.'' *See* SR–CBOE–2022–027, *available at https://www.cboe.com/us/options/regulation/rule_filings/* (last visited July 22, 2022). Accordingly, based on a review of Cboe's rulebook as well as Cboe's regulatory and trading notices to their members, the Exchange believes Cboe has not yet implemented penny pricing in VIX options.

[9] *See id.* The Exchange notes that part of the justification for the proposal to list VIX options in penny increments was based on the fact that if the Penny Interval Program (*see* Exchange Rule 510(c) *and* MIAX Options Penny Class List, *available at https://www.miaxoptions.com/options-penny-pilot*) was open to singly-listed options (and not just multiply-listed options classes), VIX options would be eligible for inclusion in the Penny Interval Program. *See* VIX Options Penny Notice, *supra* note 5. Although volume in SPIKES options does not currently meet the requirements of the Penny Interval Program, the Commission has previously allowed singly-listed options to be quoted in penny increments when such options, irrespective of volume, were designed to track the same indexes as multiply-listed options that were in the pilot version (at the time) of the Penny Interval Program. *See* Securities Exchange Act Release No. 56565 (September 27, 2007), 72 FR 56403, 56406 (October 3, 2007) (SR–CBOE–2007–98) (approving Cboe's proposal to list and trade XSP and DJX options in penny increments).

[10] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 7.

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. The proposed rule change will not impose any burden on intramarket competition that is not necessary or appropriate, because all Exchange Members will be able to trade SPIKES options in the proposed minimum trading increments.

The proposed rule change will not impose any burden on intermarket competition that is not necessary or appropriate, because it will permit SPIKES options to have pricing consistent with the pricing of a competitive product, VIX options, that currently trades in increments of $0.01 or $0.05.

Additionally, the proposed rule change to permit SPIKES options to be listed in penny and nickel increments may relieve any burden on, or otherwise promote, competition, as it will allow market participants to trade these options at the same level of granularity as permitted for competitor products. The Exchange also expects the more granular pricing to lead to narrowing of the bid-ask spread for these options, which the Exchange believes will increase order flow and price competition in SPIKES options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 [15] and Rule 19b–4(f)(6) thereunder.[16]

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2022–30 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–MIAX–2022–30. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2022–30 and should be submitted on or before October 20, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21066 Filed 9–28–22; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95900; File No. SR–Phlx–2022–36]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Clearly Erroneous Rules

September 23, 2022.

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 September 20, 2022, Nasdaq PHLX LLC (''Phlx'' or ''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 Equity 4, Rule 3312.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* 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 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

On September 1, 2022, the Commission approved the proposal of Cboe BZX Exchange, Inc. (''Cboe BZX'') to (1) adopt on a permanent basis the pilot program for clearly erroneous executions in Cboe BZX Rule 11.17 and (2) limit the circumstances where clearly erroneous review would continue to be available during regular trading hours (*i.e.,* Market Hours) [3] when the Limit Up-Limit Down (''LULD'') Plan to Address Extraordinary Market Volatility (the ''LULD Plan'') [4] already provides similar protections for trades occurring at prices that may be deemed erroneous.[5]

The Exchange now proposes to adopt the same changes in Equity 4, Rule 3312 (Clearly Erroneous Transactions). The Exchange believes that these changes are appropriate as the LULD Plan has been approved by the Commission on a permanent basis,[6] and in light of amendments to the LULD Plan, including changes to the applicable Price Bands [7] around the open and close of trading.

Proposal To Make the Clearly Erroneous Pilot Permanent

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 4, Rule 3312 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[8] Following this, on September 30, 2010, the Exchange adopted changes to conform its Rule 3312 to Nasdaq's and BX's rules 11890.[9] In 2013, the Exchange adopted a provision designed to address the operation of the LULD Plan.[10] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[11] These changes are currently scheduled to operate for a pilot period that would end at the close of business on October 20, 2022.[12]

When it originally approved the clearly erroneous pilot, the Commission explained that the changes were ''being implemented on a pilot basis so that the Commission and the Exchanges can monitor the effects of the pilot on the markets and investors, and consider appropriate adjustments, as necessary.'' [13] In the 12 years since that time, the Exchange and other national securities exchanges have gained considerable experience in the operation of the rule, as amended on a pilot basis. Based on that experience, the Exchange believes that the program should be allowed to continue on a permanent basis so that equities market participants and investors can benefit from the increased certainty provided by the amended rule.

The clearly erroneous pilot was implemented following a severe disruption in the U.S. equities markets on May 6, 2010 (''Flash Crash'') to ''provide greater transparency and certainty to the process of breaking trades.'' [14] Largely, the pilot reduced the discretion of the Exchange, other national securities exchanges, and Financial Industry Regulatory Authority (''FINRA'') to deviate from the objective standards in their respective rules when dealing with potentially erroneous transactions. The pilot has thus helped afford greater certainty to Members and investors about when trades will be deemed erroneous pursuant to self-regulatory organization (''SRO'') rules and has provided a more transparent process for conducting such reviews. The Exchange proposes to make the current pilot permanent so that market participants can continue to benefit from the increased certainty afforded by the current rule.

Amendments to the Clearly Erroneous Rules

When the Participants to the LULD Plan filed to introduce the Limit Up-Limit Down (''LULD'') mechanism, itself a response to the Flash Crash, a handful of commenters noted the potential discordance between the clearly erroneous rules and the Price Bands used to limit the price at which trades would be permitted to be executed pursuant to the LULD Plan. For example, two commenters requested that the clearly erroneous rules be amended so the presumption would be that trades executed within the Price Bands would not be subject to review.[15] While the Participants acknowledged that the potential to prevent clearly erroneous executions would be a ''key benefit'' of the LULD Plan, the Participants decided not to amend the clearly erroneous rules at that time.[16] In the years since, industry feedback has continued to reflect a desire to eliminate the discordance between the LULD mechanism and the clearly erroneous rules so that market participants would have more certainty that trades executed with the Price Bands would stand. For example, the Equity Market Structure Advisory Committee (''EMSAC'') Market Quality Subcommittee included in its April 19, 2016 status report a preliminary recommendation that

[3] *See* Securities Exchange Act Release No. 95658 (September 1, 2022) (SR–CboeBZX–2022–037).

[4] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[5] The term ''Market Hours'' means the period of time beginning at 9:30 a.m. ET and ending at 4:00 p.m. ET (or such earlier time as may be designated by the Exchange on a day when PSX closes early). *See* Equity 1, Section 1(g). The Exchange will make conforming changes throughout Rule 3312 to replace references to ''Regular Trading Hours'' or ''Regular Market Session'' with ''Market Hours,'' which is the correct defined term.

[6] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (''Notice''); 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631) (''Amendment Eighteen'').

[7] ''Price Bands'' refers to the term provided in Section V of the LULD Plan.

[8] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[9] *See* Securities Exchange Act Release No. 63023 (September 30, 2010), 75 FR 61802 (October 6, 2010) (SR–Phlx–2010–125).

[10] *See* Securities Exchange Act Release No. 68820 (February 1, 2013), 78 FR 9436 (February 8, 2013) (SR–Phlx–2013–12).

[11] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–Phlx–2014–27).

[12] *See* Securities Exchange Act Release No. 95331 (July 20, 2022), 87 FR 44447 (July 26, 2022) (SR–Phlx–2022–31).

[13] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[14] *Id.*

[15] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) (n. 33505).

[16] *Id.*

clearly erroneous rules be amended to conform to the Price Bands—*i.e.,* ''any trade that takes place within the band would stand and not be broken and trades outside the LU/LD bands would be eligible for the consideration of the Clearly Erroneous rules.'' [17]

The Exchange believes that it is important for there to be some mechanism to ensure that investors' orders are either not executed at clearly erroneous prices or are subsequently busted as needed to maintain a fair and orderly market. At the same time, the Exchange believes that the LULD Plan, as amended, would provide sufficient protection for trades executed during Market Hours. Indeed, the LULD mechanism could be considered to offer superior protection as it prevents potentially erroneous trades from being executed in the first instance. After gaining experience with the LULD Plan, the Exchange now believes that it is appropriate to largely eliminate clearly erroneous review during Market Hours when Price Bands are in effect. Thus, as proposed, trades executed within the Price Bands would stand, barring one of a handful of identified scenarios where such review may still be necessary for the protection of investors. The Exchange believes that this change would be beneficial for the U.S. equities markets as it would ensure that trades executed within the Price Bands are subject to clearly erroneous review in only rare circumstances, resulting in greater certainty for Members and investors.

The current LULD mechanism for addressing extraordinary market volatility is available solely during Market Hours. Thus, trades during the Exchange's Pre-Market [18] or Post-Market Hours [19] would not benefit from this protection and could ultimately be executed at prices that may be considered erroneous. For this reason, the Exchange proposes that transactions executed during Pre-Market or Post-Market Hours would continue to be reviewable as clearly erroneous. Continued availability of the clearly erroneous rule during Pre- and Post-Market Hours would therefore ensure that investors have appropriate recourse when erroneous trades are executed outside of the hours where similar protection can be provided by the LULD Plan. Further, the proposal is designed to eliminate the potential discordance between clearly erroneous review and LULD Price Bands, which does not exist outside of Market Hours because the LULD Plan is not in effect. Thus, the Exchange believes that it is appropriate to continue to allow transactions to be eligible for clearly erroneous review if executed outside of Market Hours.

On the other hand, there would be much more limited potential to request that a transaction be reviewed as potentially erroneous during Market Hours. With the introduction of the LULD mechanism in 2013, clearly erroneous trades are largely prevented by the requirement that trades be executed within the Price Bands. In addition, in 2019, Amendment Eighteen to the LULD Plan eliminated double-wide Price Bands: (1) at the Open, and (2) at the Close for Tier 2 NMS Stocks 2 with a Reference Price above $3.00.[20] Due to these changes, the Exchange believes that the Price Bands would provide sufficient protection to investor orders such that clearly erroneous review would no longer be necessary during Market Hours. As the Participants to the LULD Plan explained in Amendment Eighteen: ''Broadly, the Limit Up-Limit Down mechanism prevents trades from happening at prices where one party to the trade would be considered 'aggrieved,' and thus could be viewed as an appropriate mechanism to supplant clearly erroneous rules.'' While the Participants also expressed concern that the Price Bands might be too wide to afford meaningful protection around the open and close of trading, amendments to the LULD Plan adopted in Amendment Eighteen narrowed Price Bands at these times in a manner that the Exchange believes is sufficient to ensure that investors' orders would be appropriately protected in the absence of clearly erroneous review. The Exchange therefore believes that it is appropriate to rely on the LULD mechanism as the primary means of preventing clearly erroneous trades during Market Hours.

At the same time, the Exchange is cognizant that there may be limited circumstances where clearly erroneous review may continue to be appropriate, even during Market Hours. Thus, the Exchange proposes to amend its clearly erroneous rules to enumerate the specific circumstances where such review would remain available during the course of Market Hours, as follows. All transactions that fall outside of these specific enumerated exceptions would be ineligible for clearly erroneous review.

First, pursuant to proposed subparagraph (C)(1)(i) of Rule 3312(a)(2), a transaction executed during Market Hours would continue to be eligible for clearly erroneous review if the transaction is not subject to the LULD Plan. In such case, the Numerical Guidelines set forth in subparagraph (C)(2) of Rule 3312(a)(2) will be applicable to such NMS Stock. While the majority of securities traded on the Exchange would be subject to the LULD Plan, certain equity securities, such as rights and warrants, are explicitly excluded from the provisions of the LULD Plan and would therefore be eligible for clearly erroneous review instead.[21] Similarly, there are instances, such as the opening auction on the primary listing market,[22] where transactions are not ordinarily subject to the LULD Plan, or circumstances where a transaction that ordinarily would have been subject to the LULD Plan is not—due, for example, to some issue with processing the Price Bands. These transactions would continue to be eligible for clearly erroneous review, effectively ensuring that such review remains available as a backstop when the LULD Plan would not prevent executions from occurring at erroneous prices in the first instance.

Second, investors would also continue to be able to request review of transactions that resulted from certain systems issues pursuant to proposed subparagraph (C)(1)(ii). This limited exception would help to ensure that trades that should not have been executed would continue to be subject to clearly erroneous review. Specifically, as proposed, transactions executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(ii) if the transaction is the result of an Exchange technology or systems issue that results in the transaction occurring outside of the applicable LULD Price Bands pursuant to Rule 3312(g), or is executed after the primary listing market for the security declares

[17] *See* EMSAC Market Quality Subcommittee, Recommendations for Rulemaking on Issues of Market Quality (November 29, 2016), available at *https://www.sec.gov/spotlight/emsac/emsac-recommendations-rulemaking-market-quality.pdf.*

[18] The term ''Pre-Market Hours'' means the period of time beginning at 8:00 a.m. ET and ending immediately prior to the commencement of Market Hours. *See* Equity 1, Section 1(g). The Exchange will make conforming changes throughout Rule 3312 to replace references to ''Pre-Opening Hours'' or ''Pre-Opening Hours Trading Session'' with ''Pre-Market Hours,'' which is the correct defined term.

[19] The term ''Post-Market Hours'' means the period of time beginning immediately after the end of Market Hours and ending at 5:00 p.m. ET. *See* Equity 1, Section 1(g). The Exchange will make conforming changes throughout Rule 3312 to replace references to ''After Hours'' or ''After Hours Trading Session'' with ''Post-Market Hours,'' which is the correct defined term.

[20] *See* Amendment Eighteen, *supra* note 6.

[21] *See* Appendix A of the LULD Plan.

[22] The initial Reference Price used to calculate Price Bands is typically set by the Opening Price on the primary listing market. *See* Section V(B) of the LULD Plan.

a regulatory trading halt, suspension, or pause pursuant to Rule 3312(i). A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D) of this Rule, by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan (''Percentage Parameters'').

Third, the Exchange proposes to narrowly allow for the review of transactions during Market Hours when the Reference Price, described in proposed subparagraph (D), is determined to be erroneous by an Officer of the Exchange or senior level employee designee. Specifically, a transaction executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(iii) of Rule 3312(a)(2) if the transaction involved, in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to the LULD Plan and resumes trading without an auction,[23] a Reference Price that is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. In such circumstances, the Exchange may use a different Reference Price pursuant to proposed subparagraph (D)(2) of this Rule. A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the new Reference Price, described in subparagraph (D)(2) below, by an amount that equals or exceeds the applicable Numerical Guidelines or Percentage Parameters, as applicable depending on whether the security is subject to the LULD Plan. Specifically, the Percentage Parameters would apply to all transactions except those in an NMS Stock that is not subject to the LULD Plan, as described in subparagraph (C)(1)(i).

In the context of a corporate action or a new issue, there may be instances where the security's Reference Price is later determined by the Exchange to be erroneous (*e.g.,* because of a bad first trade for a new issue), and subsequent LULD Price Bands are calculated from that incorrect Reference Price. In determining whether the Reference Price is erroneous in such instances, the Exchange would generally look to see if such Reference Price clearly deviated from the theoretical value of the security. In such cases, the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing.[24] In the foregoing instances, the theoretical value of the security would be used as the new Reference Price when applying the Percentage Parameters under the LULD Plan (or Numerical Guidelines if the transaction is in an NMS Stock that is not subject to the LULD Plan) to determine whether executions would be cancelled as clearly erroneous.

The following illustrate the proposed application of the rule in the context of a corporate action or new issue:

Example 1:

1. ABCD is subject to a corporate action, 1 for 10 reverse split, and the previous day close was $5, but the new theoretical price based on the terms of the corporate action is $50.

2. The security opens at $5, with LULD bands at $4.50 × $5.50.

3. The bands will be calculated correctly but the security is trading at an erroneous price based on the valuation of the remaining outstanding shares.

4. The theoretical price of $50 would be used as the new Reference Price when applying LULD bands to determine if executions would be cancelled as clearly erroneous.

Example 2:

1. ABCD is subject to a corporate action, the company is doing a spin off where a new issue will be listed, BCDE. ABCD trades at $50, and the spinoff company is worth ⅕ of ABCD.

2. BCDE opens at $50 in the belief it is the same company as ABCD.

3. The theoretical values of the two companies are ABCD $40 and BCDE $10.

4. BCDE would be deemed to have had an incorrect Reference Price and the theoretical value of $10 would be used as the new Reference Price when applying the LULD Bands to determine if executions would be cancelled as clearly erroneous.

Example 3:

1. ABCD is an uplift from the OTC market, the prior days close on the OTC market was $20.

2. ABCD opens trading on the new listing exchange at $0.20 due to an erroneous order entry.

3. The new Reference Price to determine clearly erroneous executions would be $20, the theoretical value of the stock from where it was last traded.

In the context of the rare situation in which a security that enters a LULD Trading Pause and resumes trading without an auction (*i.e.,* reopens with quotations), the LULD Plan requires that the new Reference Price in this instance be established by using the mid-point of the best bid and offer (''BBO'') on the primary listing exchange at the reopening time.[25] This can result in a Reference Price and subsequent LULD Price Band calculation that is significantly away from the security's last traded or more relevant price, especially in less liquid names. In such rare instances, the Exchange is proposing to use a different Reference Price that is based on the prior LULD Band that triggered the Trading Pause, rather than the midpoint of the BBO.

The following example illustrates the proposed application of the rule in the context of a security that reopens without an auction:

Example 4:

1. ABCD stock is trading at $20, with LULD Bands at $18 × $22.

2. An incoming buy order causes the stock to enter a Limit State Trading Pause and then a Trading Pause at $22.

3. During the Trading Pause, the buy order causing the Trading Pause is cancelled.

4. At the end of the 5-minute halt, there is no crossed interest for an auction to occur, thus trading would resume on a quote.

5. Upon resumption, a quote that was available prior to the Trading Pause (*e.g.,* a quote was resting on the book prior to the Trading Pause), is widely set at $10 × $90.

6. The Reference Price upon resumption is $50 (mid-point of BBO).

7. The SIP will use this Reference Price and publish LULD Bands of $45 × $55 (*i.e.,* far away from BBO prior to the halt).

8. The bands will be calculated correctly, but the $50 Reference Price is subsequently determined to be incorrect as the price clearly deviated from where it previously traded prior to the Trading Pause.

[23] The Exchange notes that the ''resumption of trading without an auction'' provision of the proposed rule text applies only to securities that enter a Trading Pause pursuant to LULD and does not apply to a corporate action or new issue.

[24] Using transaction data reported to the FINRA OTC Reporting Facility, FINRA disseminates via the Trade Data Dissemination Service a final closing report for OTC equity securities for each business day that includes, among other things, each security's closing last sale price.

[25] *See* LULD Plan, Section I(U) and V(C)(1).

9. The new Reference Price would be $22 (*i.e.,* the last effective Price Band that was in a limit state before the Trading Pause), and the LULD Bands would be applied to determine if the executions should be cancelled as clearly erroneous.

In all of the foregoing situations, investors would be left with no remedy to request clearly erroneous review without the proposed carveouts in subparagraph (C)(1)(iii) because the trades occurred within the LULD Price Bands (albeit LULD Price Bands that were calculated from an erroneous Reference Price). The Exchange believes that removing the current ability for the Exchange to review in these narrow circumstances would lessen investor protections.

Numerical Guidelines

Today, subparagraph (C)(i) defines the Numerical Guidelines that are used to determine if a transaction is deemed clearly erroneous during Market Hours, or during the Pre-Market and Post-Market Hours. With respect to Market Hours, trades are generally deemed clearly erroneous if the execution price differs from the Reference Price (*i.e.,* last sale) by 10% if the Reference Price is greater than $0.00 up to and including $25.00; 5% if the Reference Price is greater than $25.00 up to and including $50.00; and 3% if the Reference Price is greater than $50.00. Wider parameters are also used for reviews for Multi-Stock Events, as described in subparagraph (C)(ii). With respect to transactions in Leveraged ETF/ETN securities executed during Market Hours, Pre-Market and Post-Market Hours, trades are deemed clearly erroneous if the execution price exceeds the Market Hours Numerical Guidelines multiplied by the leverage multiplier.

Given the changes described in this proposed rule change, the Exchange proposes to amend the way that the Numerical Guidelines are applied during Market Hours in the handful of instances where clearly erroneous review would continue to be available. Specifically during Market Hours, the Exchange would continue to apply the Numerical Guidelines, which would be relocated from subparagraph (C)(i) to (C)(2)(i) under this proposal, to transactions eligible for review pursuant proposed subparagraph (C)(1)(i) (*i.e.,* transactions in NMS Stocks that are not subject to the LULD Plan). In addition, as applied to the circumstances described in proposed subparagraphs (C)(1)(ii) and (iii), the Exchange would not apply the Numerical Guidelines in proposed subparagraph (C)(2)(i) during Market Hours, and would instead apply the Percentage Parameters used to calculate Price Bands, as set forth in Appendix A to the LULD Plan. Without this change, a transaction that would otherwise stand if Price Bands were properly applied to the transaction may end up being subject to review and deemed clearly erroneous solely due to the fact that the Price Bands were not available due to a systems or other issue. The Exchange believes that it makes more sense to instead base the Price Bands on the same parameters as would otherwise determine whether the trade would have been allowed to execute within the Price Bands. The Exchange also proposes to modify the Numerical Guidelines applicable to leveraged ETF/ETN securities during Market Hours. As noted above, the Numerical Guidelines will only be applicable to transactions eligible for review pursuant subparagraph (C)(1)(i) (*i.e.,* to NMS Stocks that are not subject to the LULD Plan). As leveraged ETF/ETN securities are subject to LULD and thus the Percentage Parameters will be applicable during Market Hours, the Exchange proposes to eliminate the Numerical Guidelines for leveraged ETF/ETN securities traded during Market Hours. However, as no Price Bands are available outside of Market Hours, the Exchange proposes to keep the existing Numerical Guidelines in place for transactions in leveraged ETF/ETN securities that occur during Pre-Market and Post-Market Hours.

The Exchange also proposes to move existing subparagraphs (C)(ii) (Multi-Stock Events Involving Twenty or More Securities) and (C)(iii) (Additional Factors) as proposed subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, and also proposes to make clear that Multi-Stock Events and Additional Factors will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during the Pre-Market or Post-Market Hours. The Exchange proposes to make similar changes to existing subparagraph (A)(iii) (Outlier Transactions) to make clear that such transactions will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during Pre-Market or Post-Market Hours. Further, given the proposal to move existing subparagraphs (C)(2) and (C)(3) to subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, the Exchange also proposes to amend applicable rule references throughout subparagraph (C)(2)(i). Further, the Exchange proposes to update applicable rule references in subparagraph (A)(iii) based on the above-described structural changes to the Rule.

Reference Price

As proposed, the Reference Price used would continue to be based on last sale and would be memorialized in proposed subparagraph (D). Continuing to use the last sale as the Reference Price is necessary for operational efficiency as it may not be possible to perform a timely clearly erroneous review if doing so required computing the arithmetic mean price of eligible reported transactions over the past five minutes, as contemplated by the LULD Plan. While this means that there would still be some differences between the Price Bands and the clearly erroneous parameters, the Exchange believes that this difference is reasonable in light of the need to ensure timely review if clearly erroneous rules are invoked. The Exchange also proposes to allow for an alternate Reference Price to be used as prescribed in proposed subparagraphs (D)(1), (2), and (3). Specifically, the Reference Price may be a value other than the consolidated last sale immediately prior to the execution(s) under review (1) in the case of Multi-Stock Events involving twenty or more securities, as described in subparagraph (C)(2)(ii) above, (2) in the case of an erroneous Reference Price, as described in subparagraph (C)(1)(iii) above,[26] or (3) in other circumstances, such as, for example, relevant news impacting a security or securities, periods of extreme market volatility, sustained illiquidity, or widespread system issues, where use of a different Reference Price is necessary for the maintenance of a fair and orderly market and the protection of investors and the public interest, provided that such circumstances occurred during Pre-Market or Post-Market Hours or are eligible for review pursuant to subparagraph (C)(1)(i).

System Disruption or Malfunction

To conform with the structural changes described above, the Exchange now proposes to remove paragraph (b)(1), System Disruption or Malfunctions, and renumber existing paragraph (b)(2) as (b)(1). Additionally,

[26] As discussed above, in the case of (C)(1)(iii)(1), the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing. In the case of (C)(1)(iii)(2), the Reference Price will be the last effective Price Band that was in a limit state before the Trading Pause.

the Exchange proposes to add rule text in renumbered (b)(1) (Senior Official Acting on Own Motion) to specify that a Senior Official, acting on his or her own motion, may review potentially erroneous transactions that occur only during Pre-Market or Post-Market Hours or that are eligible for review pursuant to proposed paragraph (a)(2)(C)(1).

The Exchange also proposes new subparagraph (C)(1)(ii) of Rule 3312(a)(2). Specifically, as described in subparagraph (C)(1)(ii), transactions occurring during Market Hours that are executed outside of the LULD Price Bands due to an Exchange technology or system issue, may be subject to clearly erroneous review pursuant to proposed paragraph (g) of Rule 3312. Proposed subparagraph (C)(1)(ii) further provides that a transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D), by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan.

Securities Subject to Limit Up-Limit Down Plan

The Exchange proposes to rename paragraph (g) (Securities Subject to LULD Plan) as ''Transactions Occurring Outside of LULD Price Bands.'' Given that proposed subparagraph (C)(1) of Rule 3312(a)(2) defines the LULD Plan, the Exchange also proposes to eliminate redundant language from paragraph (g). Finally, the Exchange also proposes to update references to the LULD Plan and Price Bands so that they are uniform throughout the Rule and to update rule references throughout the paragraph to conform to the structural changes to the Rule described above.

Conforming Changes

In connection with the changes proposed above, the Exchange proposes to make a conforming change in paragraph (a)(2) to replace the reference to ''Numerical Guidelines'' to ''guidelines'' as clearly erroneous review will now be based on both the existing Numerical Guidelines and the Percentage Parameters in the manner specified above. In addition, the Exchange proposes to modify the text of paragraphs (e) (Fees), (h) (Multi-Day Event), and (i) (Trading Halts) to reference the Percentage Parameters as well as the Numerical Guidelines, and to update rule references therein to conform to the structural changes to the Rule described above. Specifically, the existing text of paragraph (e) provides that adjustments or voluntary breaks negotiated by the Exchange to trades executed at prices that meet the Numerical Guidelines set forth in (a)(2)(C)(i) count as breaks by the Exchange for purposes of this paragraph. The Exchange now proposes to amend the rule text to state that adjustments or voluntary breaks negotiated by the Exchange to trades executed at prices that meet the Percentage Parameters or Numerical Guidelines set forth in (a)(2)(C)(2) count as breaks by the Exchange for purposes of this paragraph.

In addition, the existing text of paragraphs (h) and (i) provides that any action taken in connection with this paragraph will be taken without regard to the Numerical Guidelines set forth in this Rule. The Exchange proposes to amend the rule text to provide that any action taken in connection with this paragraph will be taken without regard to the Percentage Parameters or Numerical Guidelines set forth in this Rule, with the Percentage Parameters being applicable to an NMS Stock subject to the LULD Plan and the Numerical Guidelines being applicable to an NMS Stock not subject to the LULD Plan.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[27] in general, and Section 6(b)(5) of the Act,[28] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

As explained in the purpose section of this proposed rule change, the current pilot was implemented following the Flash Crash to bring greater transparency to the process for conducting clearly erroneous reviews, and to help assure that the review process is based on clear, objective, and consistent rules across the U.S. equities markets. The Exchange believes that the amended clearly erroneous rules have been successful in that regard and have thus furthered fair and orderly markets. Specifically, the Exchange believes that the pilot has successfully ensured that such reviews are conducted based on objective and consistent standards across SROs and has therefore afforded greater certainty to Members and investors. The Exchange therefore believes that making the current pilot a permanent program is appropriate so that equities market participants can continue to reap the benefits of a clear, objective, and transparent process for conducting clearly erroneous reviews. In addition, the Exchange understands that the other U.S. equities exchanges and FINRA will also file largely identical proposals to make their respective clearly erroneous pilots permanent. The Exchange therefore believes that the proposed rule change would promote transparency and uniformity across markets concerning review of transactions as clearly erroneous and would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors, and the public interest.

Similarly, the Exchange believes that it is consistent with just and equitable principles of trade to limit the availability of clearly erroneous review during Market Hours. The LULD Plan was approved by the Commission to operate on a permanent rather than pilot basis. As a number of market participants have noted, the LULD Plan provides protections that ensure that investors' orders are not executed at prices that may be considered clearly erroneous. Further, amendments to the LULD Plan approved in Amendment Eighteen serve to ensure that the Price Bands established by the LULD Plan are ''appropriately tailored to prevent trades that are so far from current market prices that they would be viewed as having been executed in error.'' [29] Thus, the Exchange believes that clearly erroneous review should only be necessary in very limited circumstances during Market Hours. Specifically, such review would only be necessary in instances where a transaction was not subject to the LULD Plan, or was the result of some form of systems issue, as detailed in the purpose section of this proposed rule change. Additionally, in narrow circumstances where the transaction was subject to the LULD Plan, a clearly erroneous review would be available in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to LULD and resumes trading without an auction, where the Reference Price is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. Thus, eliminating clearly

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

[29] *See* Amendment Eighteen, *supra* note 6.

erroneous review in all other instances will serve to increase certainty for Members and investors that trades executed during Market Hours would typically stand and would not be subject to review.

Given the fact that clearly erroneous review would largely be limited to transactions that were not subject to the LULD Plan, the Exchange also believes that it is necessary to change the parameters used to determine whether a trade is clearly erroneous. Specifically, due to the different parameters currently used for clearly erroneous review and for determining Price Bands, it is possible that a trade that would have been permitted to execute within the Price Bands would later be deemed clearly erroneous, if, for example, a systems issue prevented the dissemination of the Price Bands. The Exchange believes that this result is contrary to the principle that trades within the Price Bands should stand, and has the potential to cause investor confusion if trades that are properly executed within the applicable parameters described in the LULD Plan are later deemed erroneous. By using consistent parameters for clearly erroneous reviews conducted during Market Hours and the calculation of the Price Bands, the Exchange believes that this change would also serve to promote greater certainty with regards to when trades may be deemed erroneous.

Finally, the proposed rule changes make organizational updates to Rule 3312 as well as minor updates and corrections to the Rule to improve readability and clarity.

B. Self-Regulatory Organization's Statement on Burden on Competition

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. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while also amending those rules to provide greater certainty to Members and investors that trades will stand if executed during Market Hours where the LULD Plan provides adequate protection against trading at erroneous prices.

The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to this proposal. Thus, the proposed rule change will help to ensure consistency across SROs without implicating any competitive issues.

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)(iii) of the Act[30] and subparagraph (f)(6) of Rule 19b–4 thereunder.[31]

A proposed rule change filed under Rule 19b–4(f)(6)[32] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[33] 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 asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative on October 1, 2022. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Exchange to coordinate its implementation of the revised clearly erroneous execution rules with the other national securities exchanges and FINRA, and will help ensure consistency across the SROs.[34] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[35]

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2022–36 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–2022–36. 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 (*http://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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File

[30] 15 U.S.C. 78s(b)(3)(A)(iii).

[31] 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 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.

[32] 17 CFR 240.19b–4(f)(6).

[33] 17 CFR 240.19b–4(f)(6)(iii).

[34] *See* SR–CboeBZX–2022–37 (July 8, 2022).

[35] 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).

Number SR–Phlx–2022–36 and should be submitted on or before October 20, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21067 Filed 9–28–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95896; File No. SR–BX–2022–017]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Clearly Erroneous Rules

September 23, 2022.

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 September 20, 2022, Nasdaq BX, Inc. (''BX'' or ''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 a proposal to amend BX Equity 11, Rule 11890 (Clearly Erroneous Transactions).

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* 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 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

On September 1, 2022, the Commission approved the proposal of Cboe BZX Exchange, Inc. (''Cboe BZX'') to (1) adopt on a permanent basis the pilot program for clearly erroneous executions in Cboe BZX Rule 11.17 and (2) limit the circumstances where clearly erroneous review would continue to be available during regular trading hours (*i.e.,* Market Hours [3]) when the Limit Up-Limit Down (''LULD'') Plan to Address Extraordinary Market Volatility (the ''LULD Plan'') [4] already provides similar protections for trades occurring at prices that may be deemed erroneous.[5]

The Exchange now proposes to adopt the same changes in Equity 11, Rule 11890 (Clearly Erroneous Transactions). The Exchange believes that these changes are appropriate as the LULD Plan has been approved by the Commission on a permanent basis,[6] and in light of amendments to the LULD Plan, including changes to the applicable Price Bands [7] around the open and close of trading.

Proposal To Make the Clearly Erroneous Pilot Permanent

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 11, Rule 11890 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[8] In 2013, the Exchange adopted a provision designed to address the operation of the LULD Plan.[9] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[10] These changes are currently scheduled to operate for a pilot period that would end at the close of business on October 20, 2022.[11]

When it originally approved the clearly erroneous pilot, the Commission explained that the changes were ''being implemented on a pilot basis so that the Commission and the Exchanges can monitor the effects of the pilot on the markets and investors, and consider appropriate adjustments, as necessary.'' [12] In the 12 years since that time, the Exchange and other national securities exchanges have gained considerable experience in the operation of the rule, as amended on a pilot basis. Based on that experience, the Exchange believes that the program should be allowed to continue on a permanent basis so that equities market participants and investors can benefit from the increased certainty provided by the amended rule.

The clearly erroneous pilot was implemented following a severe disruption in the U.S. equities markets on May 6, 2010 (''Flash Crash'') to ''provide greater transparency and certainty to the process of breaking trades.'' [13] Largely, the pilot reduced the

[36] 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. 95658 (September 1, 2022) (SR–CboeBZX–2022–037).

[4] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[5] The term ''Market Hours'' means the period of time beginning at 9:30 a.m. ET and ending at 4:00 p.m. ET (or such earlier time as may be designated by the Exchange on a day when the Exchange closes early). *See* Equity 1, Section 1(a)(13). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''Regular Trading Hours'' and ''Regular Market Session'' with ''Market Hours,'' which is the correct defined term.

[6] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (''Notice''); 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631) (''Amendment Eighteen'').

[7] ''Price Bands'' refers to the term provided in Section V of the LULD Plan.

[8] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–BX–2010–040).

[9] *See* Securities Exchange Act Release No. 68818 (February 1, 2013), 78 FR 9100 (February 7, 2013) (SR–BX–2013–010).

[10] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–BX–2014–021).

[11] *See* Securities Exchange Act Release No. 95332 (July 20, 2022), 87 FR 44471 (July 26, 2022) (SR–BX–2022–011).

[12] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–BX–2010–040).

[13] *Id.*

discretion of the Exchange, other national securities exchanges, and Financial Industry Regulatory Authority (''FINRA'') to deviate from the objective standards in their respective rules when dealing with potentially erroneous transactions. The pilot has thus helped afford greater certainty to Members and investors about when trades will be deemed erroneous pursuant to self-regulatory organization (''SRO'') rules and has provided a more transparent process for conducting such reviews. The Exchange proposes to make the current pilot permanent so that market participants can continue to benefit from the increased certainty afforded by the current rule.

Amendments to the Clearly Erroneous Rules

When the Participants to the LULD Plan filed to introduce the Limit Up-Limit Down (''LULD'') mechanism, itself a response to the Flash Crash, a handful of commenters noted the potential discordance between the clearly erroneous rules and the Price Bands used to limit the price at which trades would be permitted to be executed pursuant to the LULD Plan. For example, two commenters requested that the clearly erroneous rules be amended so the presumption would be that trades executed within the Price Bands would not be subject to review.[14] While the Participants acknowledged that the potential to prevent clearly erroneous executions would be a ''key benefit'' of the LULD Plan, the Participants decided not to amend the clearly erroneous rules at that time.[15] In the years since, industry feedback has continued to reflect a desire to eliminate the discordance between the LULD mechanism and the clearly erroneous rules so that market participants would have more certainty that trades executed with the Price Bands would stand. For example, the Equity Market Structure Advisory Committee (''EMSAC'') Market Quality Subcommittee included in its April 19, 2016 status report a preliminary recommendation that clearly erroneous rules be amended to conform to the Price Bands—*i.e.,* ''any trade that takes place within the band would stand and not be broken and trades outside the LU/LD bands would be eligible for the consideration of the Clearly Erroneous rules.'' [16]

The Exchange believes that it is important for there to be some mechanism to ensure that investors' orders are either not executed at clearly erroneous prices or are subsequently busted as needed to maintain a fair and orderly market. At the same time, the Exchange believes that the LULD Plan, as amended, would provide sufficient protection for trades executed during Market Hours. Indeed, the LULD mechanism could be considered to offer superior protection as it prevents potentially erroneous trades from being executed in the first instance. After gaining experience with the LULD Plan, the Exchange now believes that it is appropriate to largely eliminate clearly erroneous review during Market Hours when Price Bands are in effect. Thus, as proposed, trades executed within the Price Bands would stand, barring one of a handful of identified scenarios where such review may still be necessary for the protection of investors. The Exchange believes that this change would be beneficial for the U.S. equities markets as it would ensure that trades executed within the Price Bands are subject to clearly erroneous review in only rare circumstances, resulting in greater certainty for Members and investors.

The current LULD mechanism for addressing extraordinary market volatility is available solely during Market Hours. Thus, trades during the Exchange's Pre-Market [17] or Post-Market Hours [18] would not benefit from this protection and could ultimately be executed at prices that may be considered erroneous. For this reason, the Exchange proposes that transactions executed during Pre-Market or Post-Market Hours would continue to be reviewable as clearly erroneous. Continued availability of the clearly erroneous rule during Pre- and Post-Market Hours would therefore ensure that investors have appropriate recourse when erroneous trades are executed outside of the hours where similar protection can be provided by the LULD Plan. Further, the proposal is designed to eliminate the potential discordance between clearly erroneous review and LULD Price Bands, which does not exist outside of Market Hours because the LULD Plan is not in effect. Thus, the Exchange believes that it is appropriate to continue to allow transactions to be eligible for clearly erroneous review if executed outside of Market Hours.

On the other hand, there would be much more limited potential to request that a transaction be reviewed as potentially erroneous during Market Hours. With the introduction of the LULD mechanism in 2013, clearly erroneous trades are largely prevented by the requirement that trades be executed within the Price Bands. In addition, in 2019, Amendment Eighteen to the LULD Plan eliminated double-wide Price Bands: (1) at the Open, and (2) at the Close for Tier 2 NMS Stocks 2 with a Reference Price above $3.00.[19] Due to these changes, the Exchange believes that the Price Bands would provide sufficient protection to investor orders such that clearly erroneous review would no longer be necessary during Market Hours. As the Participants to the LULD Plan explained in Amendment Eighteen: ''Broadly, the Limit Up-Limit Down mechanism prevents trades from happening at prices where one party to the trade would be considered 'aggrieved,' and thus could be viewed as an appropriate mechanism to supplant clearly erroneous rules.'' While the Participants also expressed concern that the Price Bands might be too wide to afford meaningful protection around the open and close of trading, amendments to the LULD Plan adopted in Amendment Eighteen narrowed Price Bands at these times in a manner that the Exchange believes is sufficient to ensure that investors' orders would be appropriately protected in the absence of clearly erroneous review. The Exchange therefore believes that it is appropriate to rely on the LULD mechanism as the primary means of preventing clearly erroneous trades during Market Hours.

At the same time, the Exchange is cognizant that there may be limited circumstances where clearly erroneous review may continue to be appropriate, even during Market Hours. Thus, the Exchange proposes to amend its clearly erroneous rules to enumerate the specific circumstances where such review would remain available during the course of Market Hours, as follows. All transactions that fall outside of these specific enumerated exceptions would

[14] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) (n. 33505).

[15] *Id.*

[16] *See* EMSAC Market Quality Subcommittee, Recommendations for Rulemaking on Issues of Market Quality (November 29, 2016), available at *https://www.sec.gov/spotlight/emsac/emsac-recommendations-rulemaking-market-quality.pdf.*

[17] The term ''Pre-Market Hours'' means the period of time beginning at 7:00 a.m. ET and ending immediately prior to the commencement of Market Hours. *See* Equity 1, Section 1(a)(13). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''Pre-Opening Hours'' or ''Pre-Opening Hours Trading Session'' with ''Pre-Market Hours,'' which is the correct defined term.

[18] The term ''Post-Market Hours'' means the period of time beginning immediately after the end of Market Hours and ending at 7:00 p.m. ET. *See* Equity 1, Section 1(a)(13). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''After Hours'' or ''After Hours Trading Session'' with ''Post-Market Hours,'' which is the correct defined term.

[19] *See* Amendment Eighteen, *supra* note 6.

be ineligible for clearly erroneous review.

First, pursuant to proposed subparagraph (C)(1)(i) of Rule 11890(a)(2), a transaction executed during Market Hours would continue to be eligible for clearly erroneous review if the transaction is not subject to the LULD Plan. In such case, the Numerical Guidelines set forth in subparagraph (C)(2) of Rule 11890(a)(2) will be applicable to such NMS Stock. While the majority of securities traded on the Exchange would be subject to the LULD Plan, certain equity securities, such as rights and warrants, are explicitly excluded from the provisions of the LULD Plan and would therefore be eligible for clearly erroneous review instead.[20] Similarly, there are instances, such as the opening auction on the primary listing market,[21] where transactions are not ordinarily subject to the LULD Plan, or circumstances where a transaction that ordinarily would have been subject to the LULD Plan is not—due, for example, to some issue with processing the Price Bands. These transactions would continue to be eligible for clearly erroneous review, effectively ensuring that such review remains available as a backstop when the LULD Plan would not prevent executions from occurring at erroneous prices in the first instance.

Second, investors would also continue to be able to request review of transactions that resulted from certain systems issues pursuant to proposed subparagraph (C)(1)(ii). This limited exception would help to ensure that trades that should not have been executed would continue to be subject to clearly erroneous review. Specifically, as proposed, transactions executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(ii) if the transaction is the result of an Exchange technology or systems issue that results in the transaction occurring outside of the applicable LULD Price Bands pursuant to Rule 11890(g), or is executed after the primary listing market for the security declares a regulatory trading halt, suspension, or pause pursuant to Rule 11890(i). A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D) of this Rule, by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan (''Percentage Parameters'').

Third, the Exchange proposes to narrowly allow for the review of transactions during Market Hours when the Reference Price, described in proposed subparagraph (D), is determined to be erroneous by an Officer of the Exchange or senior level employee designee. Specifically, a transaction executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(iii) of Rule 11890(a)(2) if the transaction involved, in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to the LULD Plan and resumes trading without an auction,[22] a Reference Price that is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. In such circumstances, the Exchange may use a different Reference Price pursuant to proposed subparagraph (D)(2) of this Rule. A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the new Reference Price, described in subparagraph (D)(2) below, by an amount that equals or exceeds the applicable Numerical Guidelines or Percentage Parameters, as applicable depending on whether the security is subject to the LULD Plan. Specifically, the Percentage Parameters would apply to all transactions except those in an NMS Stock that is not subject to the LULD Plan, as described in subparagraph (C)(1)(i).

In the context of a corporate action or a new issue, there may be instances where the security's Reference Price is later determined by the Exchange to be erroneous (*e.g.,* because of a bad first trade for a new issue), and subsequent LULD Price Bands are calculated from that incorrect Reference Price. In determining whether the Reference Price is erroneous in such instances, the Exchange would generally look to see if such Reference Price clearly deviated from the theoretical value of the security. In such cases, the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing.[23] In the foregoing instances, the theoretical value of the security would be used as the new Reference Price when applying the Percentage Parameters under the LULD Plan (or Numerical Guidelines if the transaction is in an NMS Stock that is not subject to the LULD Plan) to determine whether executions would be cancelled as clearly erroneous.

The following illustrate the proposed application of the rule in the context of a corporate action or new issue:

Example 1

1. ABCD is subject to a corporate action, 1 for 10 reverse split, and the previous day close was $5, but the new theoretical price based on the terms of the corporate action is $50
2. The security opens at $5, with LULD bands at $4.50 × $5.50
3. The bands will be calculated correctly but the security is trading at an erroneous price based on the valuation of the remaining outstanding shares
4. The theoretical price of $50 would be used as the new Reference Price when applying LULD bands to determine if executions would be cancelled as clearly erroneous

Example 2

1. ABCD is subject to a corporate action, the company is doing a spin off where a new issue will be listed, BCDE. ABCD trades at $50, and the spinoff company is worth ⅕ of ABCD
2. BCDE opens at $50 in the belief it is the same company as ABCD
3. The theoretical values of the two companies are ABCD $40 and BCDE $10
4. BCDE would be deemed to have had an incorrect Reference Price and the theoretical value of $10 would be used as the new Reference Price when applying the LULD Bands to determine if executions would be cancelled as clearly erroneous

[20] *See* Appendix A of the LULD Plan.

[21] The initial Reference Price used to calculate Price Bands is typically set by the Opening Price on the primary listing market. *See* Section V(B) of the LULD Plan.

[22] The Exchange notes that the ''resumption of trading without an auction'' provision of the proposed rule text applies only to securities that enter a Trading Pause pursuant to LULD and does not apply to a corporate action or new issue.

[23] Using transaction data reported to the FINRA OTC Reporting Facility, FINRA disseminates via the Trade Data Dissemination Service a final closing report for OTC equity securities for each business day that includes, among other things, each security's closing last sale price.

Example 3

1. ABCD is an uplift from the OTC market, the prior days close on the OTC market was $20
2. ABCD opens trading on the new listing exchange at $0.20 due to an erroneous order entry
3. The new Reference Price to determine clearly erroneous executions would be $20, the theoretical value of the stock from where it was last traded

In the context of the rare situation in which a security that enters a LULD Trading Pause and resumes trading without an auction (*i.e.,* reopens with quotations), the LULD Plan requires that the new Reference Price in this instance be established by using the mid-point of the best bid and offer (''BBO'') on the primary listing exchange at the reopening time.[24] This can result in a Reference Price and subsequent LULD Price Band calculation that is significantly away from the security's last traded or more relevant price, especially in less liquid names. In such rare instances, the Exchange is proposing to use a different Reference Price that is based on the prior LULD Band that triggered the Trading Pause, rather than the midpoint of the BBO.

The following example illustrates the proposed application of the rule in the context of a security that reopens without an auction:

Example 4

1. ABCD stock is trading at $20, with LULD Bands at $18 × $22
2. An incoming buy order causes the stock to enter a Limit State Trading Pause and then a Trading Pause at $22
3. During the Trading Pause, the buy order causing the Trading Pause is cancelled
4. At the end of the 5-minute halt, there is no crossed interest for an auction to occur, thus trading would resume on a quote
5. Upon resumption, a quote that was available prior to the Trading Pause (*e.g.,* a quote was resting on the book prior to the Trading Pause), is widely set at $10 × $90
6. The Reference Price upon resumption is $50 (mid-point of BBO)
7. The SIP will use this Reference Price and publish LULD Bands of $45 × $55 (*i.e.,* far away from BBO prior to the halt)
8. The bands will be calculated correctly, but the $50 Reference Price is subsequently determined to be incorrect as the price clearly deviated from where it previously traded prior to the Trading Pause
9. The new Reference Price would be $22 (*i.e.,* the last effective Price Band that was in a limit state before the Trading Pause), and the LULD Bands would be applied to determine if the executions should be cancelled as clearly erroneous

In all of the foregoing situations, investors would be left with no remedy to request clearly erroneous review without the proposed carveouts in subparagraph (C)(1)(iii) because the trades occurred within the LULD Price Bands (albeit LULD Price Bands that were calculated from an erroneous Reference Price). The Exchange believes that removing the current ability for the Exchange to review in these narrow circumstances would lessen investor protections.

Numerical Guidelines

Today, subparagraph (C)(1) defines the Numerical Guidelines that are used to determine if a transaction is deemed clearly erroneous during Market Hours, or during the Pre-Market and Post-Market Hours. With respect to Market Hours, trades are generally deemed clearly erroneous if the execution price differs from the Reference Price (*i.e.,* last sale) by 10% if the Reference Price is greater than $0.00 up to and including $25.00; 5% if the Reference Price is greater than $25.00 up to and including $50.00; and 3% if the Reference Price is greater than $50.00. Wider parameters are also used for reviews for Multi-Stock Events, as described in subparagraph (C)(2). With respect to transactions in Leveraged ETF/ETN securities executed during Market Hours, Pre-Market and Post-Market Hours, trades are deemed clearly erroneous if the execution price exceeds the Market Hours Numerical Guidelines multiplied by the leverage multiplier.

Given the changes described in this proposed rule change, the Exchange proposes to amend the way that the Numerical Guidelines are applied during Market Hours in the handful of instances where clearly erroneous review would continue to be available. Specifically during Market Hours, the Exchange would continue to apply the Numerical Guidelines, which would be relocated from subparagraph (C)(1) to (C)(2)(i) under this proposal, to transactions eligible for review pursuant proposed subparagraph (C)(1)(i) (*i.e.,* transactions in NMS Stocks that are not subject to the LULD Plan). In addition, as applied to the circumstances described in proposed subparagraphs (C)(1)(ii) and (iii), the Exchange would not apply the Numerical Guidelines in proposed subparagraph (C)(2)(i) during Market Hours, and would instead apply the Percentage Parameters used to calculate Price Bands, as set forth in Appendix A to the LULD Plan. Without this change, a transaction that would otherwise stand if Price Bands were properly applied to the transaction may end up being subject to review and deemed clearly erroneous solely due to the fact that the Price Bands were not available due to a systems or other issue. The Exchange believes that it makes more sense to instead base the Price Bands on the same parameters as would otherwise determine whether the trade would have been allowed to execute within the Price Bands. The Exchange also proposes to modify the Numerical Guidelines applicable to leveraged ETF/ETN securities during Market Hours. As noted above, the Numerical Guidelines will only be applicable to transactions eligible for review pursuant subparagraph (C)(1)(i) (*i.e.,* to NMS Stocks that are not subject to the LULD Plan). As leveraged ETF/ETN securities are subject to LULD and thus the Percentage Parameters will be applicable during Market Hours, the Exchange proposes to eliminate the Numerical Guidelines for leveraged ETF/ETN securities traded during Market Hours. However, as no Price Bands are available outside of Market Hours, the Exchange proposes to keep the existing Numerical Guidelines in place for transactions in leveraged ETF/ETN securities that occur during Pre-Market and Post-Market Hours.

The Exchange also proposes to move existing subparagraphs (C)(2) (Multi-Stock Events Involving Twenty or More Securities) and (C)(3) (Additional Factors) as proposed subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, and also proposes to make clear that Multi-Stock Events and Additional Factors will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during the Pre-Market or Post-Market Hours. The Exchange proposes to make similar changes to existing subparagraph (A)(iii) (Outlier Transactions) to make clear that such transactions will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during Pre-Market or Post-Market Hours. Further, given the proposal to move existing subparagraphs (C)(2) and (C)(3) to subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, the Exchange also proposes to amend applicable rule references throughout subparagraph (C)(2)(i). Further, the Exchange proposes to update applicable rule references in

[24] *See* LULD Plan, Section I(U) and V(C)(1).

subparagraph (A)(iii) based on the above-described structural changes to the Rule.

Reference Price

As proposed, the Reference Price used would continue to be based on last sale and would be memorialized in proposed subparagraph (D). Continuing to use the last sale as the Reference Price is necessary for operational efficiency as it may not be possible to perform a timely clearly erroneous review if doing so required computing the arithmetic mean price of eligible reported transactions over the past five minutes, as contemplated by the LULD Plan. While this means that there would still be some differences between the Price Bands and the clearly erroneous parameters, the Exchange believes that this difference is reasonable in light of the need to ensure timely review if clearly erroneous rules are invoked. The Exchange also proposes to allow for an alternate Reference Price to be used as prescribed in proposed subparagraphs (D)(1), (2), and (3). Specifically, the Reference Price may be a value other than the consolidated last sale immediately prior to the execution(s) under review (1) in the case of Multi-Stock Events involving twenty or more securities, as described in subparagraph (C)(2)(ii) above, (2) in the case of an erroneous Reference Price, as described in subparagraph (C)(1)(iii) above,[25] or (3) in other circumstances, such as, for example, relevant news impacting a security or securities, periods of extreme market volatility, sustained illiquidity, or widespread system issues, where use of a different Reference Price is necessary for the maintenance of a fair and orderly market and the protection of investors and the public interest, provided that such circumstances occurred during Pre-Market or Post-Market Hours or are eligible for review pursuant to subparagraph (C)(1)(i).

System Disruption or Malfunction

To conform with the structural changes described above, the Exchange now proposes to remove paragraph (b)(i), System Disruption or Malfunctions, and renumber existing paragraph (b)(ii) as (b)(i). Additionally, the Exchange proposes to add rule text in renumbered (b)(i) (Senior Official Acting on Own Motion) to specify that a Senior Official, acting on his or her own motion, may review potentially erroneous transactions that occur only during Pre-Market or Post-Market Hours or that are eligible for review pursuant to proposed paragraph (a)(2)(C)(1).

The Exchange also proposes new subparagraph (C)(1)(ii) of Rule 11890(a)(2). Specifically, as described in subparagraph (C)(1)(ii), transactions occurring during Market Hours that are executed outside of the LULD Price Bands due to an Exchange technology or system issue, may be subject to clearly erroneous review pursuant to proposed paragraph (g) of Rule 11890. Proposed subparagraph (C)(1)(ii) further provides that a transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D), by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan.

Securities Subject to Limit Up-Limit Down Plan

The Exchange proposes to rename paragraph (g) (Securities Subject to LULD Plan) as ''Transactions Occurring Outside of LULD Price Bands.'' Given that proposed subparagraph (C)(1) of Rule 11890(a)(2) defines the LULD Plan, the Exchange also proposes to eliminate redundant language from paragraph (g). Finally, the Exchange also proposes to update references to the LULD Plan and Price Bands so that they are uniform throughout the Rule and to update rule references throughout the paragraph to conform to the structural changes to the Rule described above.

Conforming Changes

In connection with the changes proposed above, the Exchange proposes to make a conforming change in paragraph (a)(2) to replace the reference to ''Numerical Guidelines'' to ''guidelines'' as clearly erroneous review will now be based on both the existing Numerical Guidelines and the Percentage Parameters in the manner specified above. In addition, the Exchange proposes to modify the text of paragraphs (e) (Fees), (h) (Multi-Day Event), and (i) (Trading Halts) to reference the Percentage Parameters as well as the Numerical Guidelines, and to update rule references therein to conform to the structural changes to the Rule described above. Specifically, the existing text of paragraph (e) provides that adjustments or voluntary breaks negotiated by the Exchange to trades executed at prices that meet the Numerical Guidelines set forth in (a)(2)(C)(1) count as breaks by the Exchange for purposes of this paragraph. The Exchange now proposes to amend the rule text to state that adjustments or voluntary breaks negotiated by the Exchange to trades executed at prices that meet the Percentage Parameters or Numerical Guidelines set forth in (a)(2)(C)(2) count as breaks by the Exchange for purposes of this paragraph.

In addition, the existing text of paragraphs (h) and (i) provides that any action taken in connection with this paragraph will be taken without regard to the Numerical Guidelines set forth in this Rule. The Exchange proposes to amend the rule text to provide that any action taken in connection with this paragraph will be taken without regard to the Percentage Parameters or Numerical Guidelines set forth in this Rule, with the Percentage Parameters being applicable to an NMS Stock subject to the LULD Plan and the Numerical Guidelines being applicable to an NMS Stock not subject to the LULD Plan.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[26] in general, and Section 6(b)(5) of the Act,[27] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

As explained in the purpose section of this proposed rule change, the current pilot was implemented following the Flash Crash to bring greater transparency to the process for conducting clearly erroneous reviews, and to help assure that the review process is based on clear, objective, and consistent rules across the U.S. equities markets. The Exchange believes that the amended clearly erroneous rules have been successful in that regard and have thus furthered fair and orderly markets. Specifically, the Exchange believes that the pilot has successfully ensured that such reviews are conducted based on objective and consistent standards

[25] As discussed above, in the case of (C)(1)(iii)(1), the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing. In the case of (C)(1)(iii)(2), the Reference Price will be the last effective Price Band that was in a limit state before the Trading Pause.

[26] 15 U.S.C. 78f(b).

[27] 15 U.S.C. 78f(b)(5).

across SROs and has therefore afforded greater certainty to Members and investors. The Exchange therefore believes that making the current pilot a permanent program is appropriate so that equities market participants can continue to reap the benefits of a clear, objective, and transparent process for conducting clearly erroneous reviews. In addition, the Exchange understands that the other U.S. equities exchanges and FINRA will also file largely identical proposals to make their respective clearly erroneous pilots permanent. The Exchange therefore believes that the proposed rule change would promote transparency and uniformity across markets concerning review of transactions as clearly erroneous and would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors, and the public interest.

Similarly, the Exchange believes that it is consistent with just and equitable principles of trade to limit the availability of clearly erroneous review during Market Hours. The LULD Plan was approved by the Commission to operate on a permanent rather than pilot basis. As a number of market participants have noted, the LULD Plan provides protections that ensure that investors' orders are not executed at prices that may be considered clearly erroneous. Further, amendments to the LULD Plan approved in Amendment Eighteen serve to ensure that the Price Bands established by the LULD Plan are ''appropriately tailored to prevent trades that are so far from current market prices that they would be viewed as having been executed in error.'' [28] Thus, the Exchange believes that clearly erroneous review should only be necessary in very limited circumstances during Market Hours. Specifically, such review would only be necessary in instances where a transaction was not subject to the LULD Plan, or was the result of some form of systems issue, as detailed in the purpose section of this proposed rule change. Additionally, in narrow circumstances where the transaction was subject to the LULD Plan, a clearly erroneous review would be available in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to LULD and resumes trading without an auction, where the Reference Price is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. Thus, eliminating clearly erroneous review in all other instances will serve to increase certainty for Members and investors that trades executed during Market Hours would typically stand and would not be subject to review.

Given the fact that clearly erroneous review would largely be limited to transactions that were not subject to the LULD Plan, the Exchange also believes that it is necessary to change the parameters used to determine whether a trade is clearly erroneous. Specifically, due to the different parameters currently used for clearly erroneous review and for determining Price Bands, it is possible that a trade that would have been permitted to execute within the Price Bands would later be deemed clearly erroneous, if, for example, a systems issue prevented the dissemination of the Price Bands. The Exchange believes that this result is contrary to the principle that trades within the Price Bands should stand, and has the potential to cause investor confusion if trades that are properly executed within the applicable parameters described in the LULD Plan are later deemed erroneous. By using consistent parameters for clearly erroneous reviews conducted during Market Hours and the calculation of the Price Bands, the Exchange believes that this change would also serve to promote greater certainty with regards to when trades may be deemed erroneous.

Finally, the proposed rule changes make organizational updates to Rule 11890 as well as minor updates and corrections to the Rule to improve readability and clarity.

B. Self-Regulatory Organization's Statement on Burden on Competition

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. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while also amending those rules to provide greater certainty to Members and investors that trades will stand if executed during Market Hours where the LULD Plan provides adequate protection against trading at erroneous prices. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to this proposal. Thus, the proposed rule change will help to ensure consistency across SROs without implicating any competitive issues.

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)(iii) of the Act [29] and subparagraph (f)(6) of Rule 19b–4 thereunder.[30]

A proposed rule change filed under Rule 19b–4(f)(6) [31] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [32] 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 asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative on October 1, 2022. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Exchange to coordinate its implementation of the revised clearly erroneous execution rules with the other national securities exchanges and FINRA, and will help ensure consistency across the SROs.[33] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[34]

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

[28] *See* Amendment Eighteen, *supra* note 6.

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 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 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.

[31] 17 CFR 240.19b–4(f)(6).

[32] 17 CFR 240.19b–4(f)(6)(iii).

[33] *See* SR–CboeBZX–2022–37 (July 8, 2022).

[34] 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).

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2022–017 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–2022–017. 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 (*http://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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2022–017 and should be submitted on or before October 20, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21065 Filed 9–28–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95903; File No. SR–MEMX–2022–27]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Update Exchange Rule 13.4(a) Regarding the Exchange's Usage of Data Feeds

September 23, 2022.

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 September 19, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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 with the Commission a proposed rule change to update Exchange Rule 13.4(a) regarding the sources of data that the Exchange utilizes for the handling, execution and routing of orders, as well as for surveillance necessary to monitor compliance with applicable securities laws and Exchange rules, with respect to certain market centers. 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

The Exchange proposes to update Exchange Rule 13.4(a) regarding the sources of data that the Exchange utilizes for the handling, execution and routing of orders, as well as for surveillance necessary to monitor compliance with applicable securities laws and Exchange rules, with respect to certain market centers. Specifically, the Exchange proposes to amend Exchange Rule 13.4(a) to reflect that it no longer utilizes direct data feeds and instead will utilize market data from the Consolidated Quotation System (''CQS'')/UTP Quotation Data Feed (''UQDF'') for such purposes with respect to the following markets centers: Cboe BYX, Cboe EDGA, Nasdaq BX, Nasdaq PSX, NYSE American, NYSE Chicago, and NYSE National.[5] The Exchange does not have a secondary source for data for these market centers.

By making the changes set forth above, the Exchange anticipates saving approximately $30,000 per month, or $360,000 annually, by discontinuing receipt of direct data feeds from the markets listed above. The Exchange determined the list of markets from which to discontinue direct data feeds because such markets represent the U.S. national securities exchanges that charge for market data but have less

[35] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange previously filed the proposal, which was effective on filing prior to August 1, 2022, the date that the Exchange transitioned over to use CQS/UQDF for the market centers listed above. *See* Securities Exchange Act Release No. 95395 (July 29, 2022), 87 FR 47799 (August 4, 2022) (SR–MEMX–2022–20) (the ''Original Proposal''). The Exchange withdrew the Original Proposal and re-filed this proposal in order to provide additional transparency and respond to a comment letter received on the Original Proposal. *See* Letter from Christopher Nagy, Research Director, Healthy Markets Association, to Vanessa Countryman, Secretary, Securities and Exchange Commission dated August 16, 2022.

than 2% market share (the majority of these exchanges have less than 1% market share). In addition, the Exchange notes that it does not anticipate that the change will negatively impact its operations or negatively impact investors. To the contrary, given the relative size of these markets and quality of quoting on such markets as compared to size and quality of quoting on the Exchange and the markets from which it continues to receive direct data feeds,[6] the Exchange does not anticipate a significant difference with respect to its implementation of applicable requirements of Regulation NMS, including SEC Rule 611 (*i.e.,* the Order Protection Rule).[7] Furthermore, with respect to the Exchange's routing services, the Exchange does not route to the markets from which it has discontinued direct data feeds nearly as much as it does to larger markets, again likely due to differences in quote quality and available liquidity at such markets. Furthermore, the Exchange's routing services are completely optional. Finally, the Exchange notes that other exchanges have made similar determinations to use direct data feeds from some markets, primarily larger markets or their own affiliates, and market data from the CQS/UQDF data feeds for other markets.[8]

The Exchange proposes for this proposed rule change to become operative on filing with the Commission.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that 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.

The Exchange believes that its proposal to update Exchange Rule 13.4(a) to reflect that it will utilize market data from the CQS/UQDF with respect to Cboe BYX, Cboe EDGA, Nasdaq BX, Nasdaq PSX, NYSE American, NYSE Chicago, and NYSE National is consistent with the Act because it will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific network processor and proprietary data feeds that the Exchange utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions. As noted above, the Exchange does not anticipate that the change will negatively impact its operations or negatively impact investors. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it provides additional specificity, clarity and transparency.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposal would enhance competition because disclosing the primary and secondary data sources utilized by the Exchange with respect to all of the exchanges enhances transparency and enables investors to better assess the quality of the Exchange's execution and routing 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

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[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[14] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[15] 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 asked the Commission to waive the 30-day operative delay.

The proposed rule change updates the sources of data the Exchange utilizes when performing: (i) order handling; (ii) order routing; (iii) order execution; and (iv) related compliance processes to reflect the use of CQS/UQDF rather than direct data feeds with respect to the market centers identified above. The Exchange states that the proposed change will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific network processor and proprietary data feeds that the Exchange utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions. The Exchange states that the proposed rule change is similar to the rules of other exchanges.[16]

The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any novel issues. Therefore, the Commission hereby waives the operative delay and designates the proposal as 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

[6] Based on publicly available information, the Exchange maintained quotations at the national best bid or offer (''NBBO'') over 25% of the time, which is third amongst all exchanges and only behind the Nasdaq Stock Market and NYSE Arca Equities. In contrast, none of the markets from which the Exchange has discontinued direct data feeds maintained a quotation at the NBBO more than 10% of the time. *See* Cboe Global Markets NBBO Quote Quality Statistics, available at: *https://www.cboe.com/us/equities/market_statistics/.*

[7] 17 CFR 242.611.

[8] *See, e.g.,* Cboe BZX Exchange, Inc. (''BZX'') Rule 11.26 (listing IEX, MEMX, MIAX Pearl, NYSE American, NYSE Chicago, and NYSE National as exchanges for which BZX uses CQS/UQDF data even though such markets offer direct data feeds); see also NYSE Arca Equities (''Arca'') Rule 7.37–E.(d) (listing IEX, MEMX, and MIAX Pearl as exchanges for which Arca uses CQS/UQDF data even though such markets offer direct data feeds).

[9] *See* supra note 5.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] *See* supra note 8.

[17] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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) [18] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–27 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–2022–27. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–27 and should be submitted on or before October 20, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

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[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95902; File No. SR–NASDAQ–2022–052]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Nasdaq Equity 11, Rule 11890

September 23, 2022.

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 September 20, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''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 Nasdaq Equity 11, Rule 11890 (Clearly Erroneous Transactions).

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* 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 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

On September 1, 2022, the Commission approved the proposal of Cboe BZX Exchange, Inc. (''Cboe BZX'') to (1) adopt on a permanent basis the pilot program for clearly erroneous executions in Cboe BZX Rule 11.17 and (2) limit the circumstances where clearly erroneous review would continue to be available during regular trading hours (*i.e.,* Market Hours) [3] when the Limit Up-Limit Down (''LULD'') Plan to Address Extraordinary Market Volatility (the ''LULD Plan'') [4] already provides similar protections for trades occurring at prices that may be deemed erroneous.[5]

The Exchange now proposes to adopt the same changes in Equity 11, Rule 11890 (Clearly Erroneous Transactions). The Exchange believes that these changes are appropriate as the LULD Plan has been approved by the Commission on a permanent basis,[6] and in light of amendments to the LULD Plan, including changes to the applicable Price Bands [7] around the open and close of trading.

Proposal To Make the Clearly Erroneous Pilot Permanent

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 11, Rule 11890 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 95658 (September 1, 2022) (SR–CboeBZX–2022–037).

[4] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[5] The term ''Market Hours'' means the period of time beginning at 9:30 a.m. ET and ending at 4:00 p.m. ET (or such earlier time as may be designated by Nasdaq on a day when Nasdaq closes early). *See* Equity 1, Section 1(a)(9). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''Regular Trading Hours'' and ''Regular Market Session'' with ''Market Hours,'' which is the correct defined term.

[6] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (''Notice''); 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631) (''Amendment Eighteen'').

[7] ''Price Bands'' refers to the term provided in Section V of the LULD Plan.

stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[8] In 2013, the Exchange adopted a provision designed to address the operation of the LULD Plan.[9] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[10] These changes are currently scheduled to operate for a pilot period that would end at the close of business on October 20, 2022.[11]

When it originally approved the clearly erroneous pilot, the Commission explained that the changes were ''being implemented on a pilot basis so that the Commission and the Exchanges can monitor the effects of the pilot on the markets and investors, and consider appropriate adjustments, as necessary.'' [12] In the 12 years since that time, the Exchange and other national securities exchanges have gained considerable experience in the operation of the rule, as amended on a pilot basis. Based on that experience, the Exchange believes that the program should be allowed to continue on a permanent basis so that equities market participants and investors can benefit from the increased certainty provided by the amended rule.

The clearly erroneous pilot was implemented following a severe disruption in the U.S. equities markets on May 6, 2010 (''Flash Crash'') to ''provide greater transparency and certainty to the process of breaking trades.'' [13] Largely, the pilot reduced the discretion of the Exchange, other national securities exchanges, and Financial Industry Regulatory Authority (''FINRA'') to deviate from the objective standards in their respective rules when dealing with potentially erroneous transactions. The pilot has thus helped afford greater certainty to Members and investors about when trades will be deemed erroneous pursuant to self-regulatory organization (''SRO'') rules and has provided a more transparent process for conducting such reviews. The Exchange proposes to make the current pilot permanent so that market participants can continue to benefit from the increased certainty afforded by the current rule.

Amendments to the Clearly Erroneous Rules

When the Participants to the LULD Plan filed to introduce the Limit Up-Limit Down (''LULD'') mechanism, itself a response to the Flash Crash, a handful of commenters noted the potential discordance between the clearly erroneous rules and the Price Bands used to limit the price at which trades would be permitted to be executed pursuant to the LULD Plan. For example, two commenters requested that the clearly erroneous rules be amended so the presumption would be that trades executed within the Price Bands would not be subject to review.[14] While the Participants acknowledged that the potential to prevent clearly erroneous executions would be a ''key benefit'' of the LULD Plan, the Participants decided not to amend the clearly erroneous rules at that time.[15] In the years since, industry feedback has continued to reflect a desire to eliminate the discordance between the LULD mechanism and the clearly erroneous rules so that market participants would have more certainty that trades executed with the Price Bands would stand. For example, the Equity Market Structure Advisory Committee (''EMSAC'') Market Quality Subcommittee included in its April 19, 2016 status report a preliminary recommendation that clearly erroneous rules be amended to conform to the Price Bands—*i.e.,* ''any trade that takes place within the band would stand and not be broken and trades outside the LU/LD bands would be eligible for the consideration of the Clearly Erroneous rules.'' [16]

The Exchange believes that it is important for there to be some mechanism to ensure that investors' orders are either not executed at clearly erroneous prices or are subsequently busted as needed to maintain a fair and orderly market. At the same time, the Exchange believes that the LULD Plan, as amended, would provide sufficient protection for trades executed during Market Hours. Indeed, the LULD mechanism could be considered to offer superior protection as it prevents potentially erroneous trades from being executed in the first instance. After gaining experience with the LULD Plan, the Exchange now believes that it is appropriate to largely eliminate clearly erroneous review during Market Hours when Price Bands are in effect. Thus, as proposed, trades executed within the Price Bands would stand, barring one of a handful of identified scenarios where such review may still be necessary for the protection of investors. The Exchange believes that this change would be beneficial for the U.S. equities markets as it would ensure that trades executed within the Price Bands are subject to clearly erroneous review in only rare circumstances, resulting in greater certainty for Members and investors.

The current LULD mechanism for addressing extraordinary market volatility is available solely during Market Hours. Thus, trades during the Exchange's Pre-Market [17] or Post-Market Hours [18] would not benefit from this protection and could ultimately be executed at prices that may be considered erroneous. For this reason, the Exchange proposes that transactions executed during Pre-Market or Post-Market Hours would continue to be reviewable as clearly erroneous.

[8] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[9] *See* Securities Exchange Act Release No. 68819 (February 1, 2013), 78 FR 9438 (February 8, 2013) (SR–NASDAQ–2013–022).

[10] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–NASDAQ–2014–044).

[11] *See* Securities Exchange Act Release No. 95329 (July 20, 2022), 87 FR 44455 (July 26, 2022) (SR–NASDAQ–2022–043).

[12] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[13] *Id.*

[14] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) (n. 33505).

[15] *Id.*

[16] *See* EMSAC Market Quality Subcommittee, Recommendations for Rulemaking on Issues of Market Quality (November 29, 2016), available at *https://www.sec.gov/spotlight/emsac/emsac-recommendations-rulemaking-market-quality.pdf.*

[17] The term ''Pre-Market Hours'' means the period of time beginning at 4:00 a.m. ET and ending immediately prior to the commencement of Market Hours. *See* Equity 1, Section 1(a)(9). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''Pre-Opening Hours'' or ''Pre-Opening Hours Trading Session'' with ''Pre-Market Hours,'' which is the correct defined term.

[18] The term ''Post-Market Hours'' means the period of time beginning immediately after the end of Market Hours and ending at 8:00 p.m. ET. *See* Equity 1, Section 1(a)(9). The Exchange will make conforming changes throughout Rule 11890 to replace references to ''After Hours'' or ''After Hours Trading Session'' with ''Post-Market Hours,'' which is the correct defined term.

Continued availability of the clearly erroneous rule during Pre- and Post-Market Hours would therefore ensure that investors have appropriate recourse when erroneous trades are executed outside of the hours where similar protection can be provided by the LULD Plan. Further, the proposal is designed to eliminate the potential discordance between clearly erroneous review and LULD Price Bands, which does not exist outside of Market Hours because the LULD Plan is not in effect. Thus, the Exchange believes that it is appropriate to continue to allow transactions to be eligible for clearly erroneous review if executed outside of Market Hours.

On the other hand, there would be much more limited potential to request that a transaction be reviewed as potentially erroneous during Market Hours. With the introduction of the LULD mechanism in 2013, clearly erroneous trades are largely prevented by the requirement that trades be executed within the Price Bands. In addition, in 2019, Amendment Eighteen to the LULD Plan eliminated double-wide Price Bands: (1) at the Open, and (2) at the Close for Tier 2 NMS Stocks 2 with a Reference Price above $3.00.[19] Due to these changes, the Exchange believes that the Price Bands would provide sufficient protection to investor orders such that clearly erroneous review would no longer be necessary during Market Hours. As the Participants to the LULD Plan explained in Amendment Eighteen: ''Broadly, the Limit Up-Limit Down mechanism prevents trades from happening at prices where one party to the trade would be considered 'aggrieved,' and thus could be viewed as an appropriate mechanism to supplant clearly erroneous rules.'' While the Participants also expressed concern that the Price Bands might be too wide to afford meaningful protection around the open and close of trading, amendments to the LULD Plan adopted in Amendment Eighteen narrowed Price Bands at these times in a manner that the Exchange believes is sufficient to ensure that investors' orders would be appropriately protected in the absence of clearly erroneous review. The Exchange therefore believes that it is appropriate to rely on the LULD mechanism as the primary means of preventing clearly erroneous trades during Market Hours.

At the same time, the Exchange is cognizant that there may be limited circumstances where clearly erroneous review may continue to be appropriate, even during Market Hours. Thus, the Exchange proposes to amend its clearly erroneous rules to enumerate the specific circumstances where such review would remain available during the course of Market Hours, as follows. All transactions that fall outside of these specific enumerated exceptions would be ineligible for clearly erroneous review.

First, pursuant to proposed subparagraph (C)(1)(i) of Rule 11890(a)(2), a transaction executed during Market Hours would continue to be eligible for clearly erroneous review if the transaction is not subject to the LULD Plan. In such case, the Numerical Guidelines set forth in subparagraph (C)(2) of Rule 11890(a)(2) will be applicable to such NMS Stock. While the majority of securities traded on the Exchange would be subject to the LULD Plan, certain equity securities, such as rights and warrants, are explicitly excluded from the provisions of the LULD Plan and would therefore be eligible for clearly erroneous review instead.[20] Similarly, there are instances, such as the opening auction on the primary listing market,[21] where transactions are not ordinarily subject to the LULD Plan, or circumstances where a transaction that ordinarily would have been subject to the LULD Plan is not—due, for example, to some issue with processing the Price Bands. These transactions would continue to be eligible for clearly erroneous review, effectively ensuring that such review remains available as a backstop when the LULD Plan would not prevent executions from occurring at erroneous prices in the first instance.

Second, investors would also continue to be able to request review of transactions that resulted from certain systems issues pursuant to proposed subparagraph (C)(1)(ii). This limited exception would help to ensure that trades that should not have been executed would continue to be subject to clearly erroneous review. Specifically, as proposed, transactions executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(ii) if the transaction is the result of an Exchange technology or systems issue that results in the transaction occurring outside of the applicable LULD Price Bands pursuant to Rule 11890(g), or is executed after the primary listing market for the security declares a regulatory trading halt, suspension, or pause pursuant to Rule 11890(i). A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D) of this Rule, by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan (''Percentage Parameters'').

Third, the Exchange proposes to narrowly allow for the review of transactions during Market Hours when the Reference Price, described in proposed subparagraph (D), is determined to be erroneous by an Officer of the Exchange or senior level employee designee. Specifically, a transaction executed during Market Hours would be eligible for clearly erroneous review pursuant to proposed subparagraph (C)(1)(iii) of Rule 11890(a)(2) if the transaction involved, in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to the LULD Plan and resumes trading without an auction,[22] a Reference Price that is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. In such circumstances, the Exchange may use a different Reference Price pursuant to proposed subparagraph (D)(2) of this Rule. A transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the new Reference Price, described in subparagraph (D)(2) below, by an amount that equals or exceeds the applicable Numerical Guidelines or Percentage Parameters, as applicable depending on whether the security is subject to the LULD Plan. Specifically, the Percentage Parameters would apply to all transactions except those in an NMS Stock that is not subject to the LULD Plan, as described in subparagraph (C)(1)(i).

In the context of a corporate action or a new issue, there may be instances where the security's Reference Price is later determined by the Exchange to be erroneous (*e.g.,* because of a bad first trade for a new issue), and subsequent LULD Price Bands are calculated from that incorrect Reference Price. In determining whether the Reference Price is erroneous in such instances, the

[19] *See* Amendment Eighteen, *supra* note 6.

[20] *See* Appendix A of the LULD Plan.

[21] The initial Reference Price used to calculate Price Bands is typically set by the Opening Price on the primary listing market. *See* Section V(B) of the LULD Plan.

[22] The Exchange notes that the ''resumption of trading without an auction'' provision of the proposed rule text applies only to securities that enter a Trading Pause pursuant to LULD and does not apply to a corporate action or new issue.

Exchange would generally look to see if such Reference Price clearly deviated from the theoretical value of the security. In such cases, the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing.[23] In the foregoing instances, the theoretical value of the security would be used as the new Reference Price when applying the Percentage Parameters under the LULD Plan (or Numerical Guidelines if the transaction is in an NMS Stock that is not subject to the LULD Plan) to determine whether executions would be cancelled as clearly erroneous.

The following illustrate the proposed application of the rule in the context of a corporate action or new issue:

Example 1

1. ABCD is subject to a corporate action, 1 for 10 reverse split, and the previous day close was $5, but the new theoretical price based on the terms of the corporate action is $50
2. The security opens at $5, with LULD bands at $4.50 × $5.50
3. The bands will be calculated correctly but the security is trading at an erroneous price based on the valuation of the remaining outstanding shares
4. The theoretical price of $50 would be used as the new Reference Price when applying LULD bands to determine if executions would be cancelled as clearly erroneous

Example 2

1. ABCD is subject to a corporate action, the company is doing a spin off where a new issue will be listed, BCDE. ABCD trades at $50, and the spinoff company is worth ⅕ of ABCD
2. BCDE opens at $50 in the belief it is the same company as ABCD
3. The theoretical values of the two companies are ABCD $40 and BCDE $10
4. BCDE would be deemed to have had an incorrect Reference Price and the theoretical value of $10 would be used as the new Reference Price when applying the LULD Bands to determine if executions would be cancelled as clearly erroneous

Example 3

1. ABCD is an uplift from the OTC market, the prior days close on the OTC market was $20
2. ABCD opens trading on the new listing exchange at $0.20 due to an erroneous order entry
3. The new Reference Price to determine clearly erroneous executions would be $20, the theoretical value of the stock from where it was last traded

In the context of the rare situation in which a security that enters a LULD Trading Pause and resumes trading without an auction (*i.e.,* reopens with quotations), the LULD Plan requires that the new Reference Price in this instance be established by using the mid-point of the best bid and offer (''BBO'') on the primary listing exchange at the reopening time.[24] This can result in a Reference Price and subsequent LULD Price Band calculation that is significantly away from the security's last traded or more relevant price, especially in less liquid names. In such rare instances, the Exchange is proposing to use a different Reference Price that is based on the prior LULD Band that triggered the Trading Pause, rather than the midpoint of the BBO.

The following example illustrates the proposed application of the rule in the context of a security that reopens without an auction:

Example 4

1. ABCD stock is trading at $20, with LULD Bands at $18 × $22
2. An incoming buy order causes the stock to enter a Limit State Trading Pause and then a Trading Pause at $22
3. During the Trading Pause, the buy order causing the Trading Pause is cancelled
4. At the end of the 5-minute halt, there is no crossed interest for an auction to occur, thus trading would resume on a quote
5. Upon resumption, a quote that was available prior to the Trading Pause (*e.g.,* a quote was resting on the book prior to the Trading Pause), is widely set at $10 × $90
6. The Reference Price upon resumption is $50 (mid-point of BBO)
7. The SIP will use this Reference Price and publish LULD Bands of $45 × $55 (*i.e.,* far away from BBO prior to the halt)
8. The bands will be calculated correctly, but the $50 Reference Price is subsequently determined to be incorrect as the price clearly deviated from where it previously traded prior to the Trading Pause
9. The new Reference Price would be $22 (*i.e.,* the last effective Price Band that was in a limit state before the Trading Pause), and the LULD Bands would be applied to determine if the executions should be cancelled as clearly erroneous

In all of the foregoing situations, investors would be left with no remedy to request clearly erroneous review without the proposed carveouts in subparagraph (C)(1)(iii) because the trades occurred within the LULD Price Bands (albeit LULD Price Bands that were calculated from an erroneous Reference Price). The Exchange believes that removing the current ability for the Exchange to review in these narrow circumstances would lessen investor protections.

Numerical Guidelines

Today, subparagraph (C)(1) defines the Numerical Guidelines that are used to determine if a transaction is deemed clearly erroneous during Market Hours, or during the Pre-Market and Post-Market Hours. With respect to Market Hours, trades are generally deemed clearly erroneous if the execution price differs from the Reference Price (*i.e.,* last sale) by 10% if the Reference Price is greater than $0.00 up to and including $25.00; 5% if the Reference Price is greater than $25.00 up to and including $50.00; and 3% if the Reference Price is greater than $50.00. Wider parameters are also used for reviews for Multi-Stock Events, as described in subparagraph (C)(2). With respect to transactions in Leveraged ETF/ETN securities executed during Market Hours, Pre-Market and Post-Market Hours, trades are deemed clearly erroneous if the execution price exceeds the Market Hours Numerical Guidelines multiplied by the leverage multiplier.

Given the changes described in this proposed rule change, the Exchange proposes to amend the way that the Numerical Guidelines are applied during Market Hours in the handful of instances where clearly erroneous review would continue to be available. Specifically during Market Hours, the Exchange would continue to apply the Numerical Guidelines, which would be relocated from subparagraph (C)(1) to (C)(2)(i) under this proposal, to transactions eligible for review pursuant proposed subparagraph (C)(1)(i) (*i.e.,* transactions in NMS Stocks that are not subject to the LULD Plan). In addition,

[23] Using transaction data reported to the FINRA OTC Reporting Facility, FINRA disseminates via the Trade Data Dissemination Service a final closing report for OTC equity securities for each business day that includes, among other things, each security's closing last sale price.

[24] *See* LULD Plan, Section I(U) and V(C)(1).

as applied to the circumstances described in proposed subparagraphs (C)(1)(ii) and (iii), the Exchange would not apply the Numerical Guidelines in proposed subparagraph (C)(2)(i) during Market Hours, and would instead apply the Percentage Parameters used to calculate Price Bands, as set forth in Appendix A to the LULD Plan. Without this change, a transaction that would otherwise stand if Price Bands were properly applied to the transaction may end up being subject to review and deemed clearly erroneous solely due to the fact that the Price Bands were not available due to a systems or other issue. The Exchange believes that it makes more sense to instead base the Price Bands on the same parameters as would otherwise determine whether the trade would have been allowed to execute within the Price Bands. The Exchange also proposes to modify the Numerical Guidelines applicable to leveraged ETF/ETN securities during Market Hours. As noted above, the Numerical Guidelines will only be applicable to transactions eligible for review pursuant subparagraph (C)(1)(i) (*i.e.,* to NMS Stocks that are not subject to the LULD Plan). As leveraged ETF/ETN securities are subject to LULD and thus the Percentage Parameters will be applicable during Market Hours, the Exchange proposes to eliminate the Numerical Guidelines for leveraged ETF/ETN securities traded during Market Hours. However, as no Price Bands are available outside of Market Hours, the Exchange proposes to keep the existing Numerical Guidelines in place for transactions in leveraged ETF/ETN securities that occur during Pre-Market and Post-Market Hours.

The Exchange also proposes to move existing subparagraphs (C)(2) (Multi-Stock Events Involving Twenty or More Securities) and (C)(3) (Additional Factors) as proposed subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, and also proposes to make clear that Multi-Stock Events and Additional Factors will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during the Pre-Market or Post-Market Hours. The Exchange proposes to make similar changes to existing subparagraph (A)(iii) (Outlier Transactions) to make clear that such transactions will only be subject to clearly erroneous review if those NMS Stocks are not subject to the LULD Plan or occur during Pre-Market or Post-Market Hours. Further, given the proposal to move existing subparagraphs (C)(2) and (C)(3) to subparagraphs (C)(2)(ii) and (C)(2)(iii), respectively, the Exchange also proposes to amend applicable rule references throughout subparagraph (C)(2)(i). Further, the Exchange proposes to update applicable rule references in subparagraph (A)(iii) based on the above-described structural changes to the Rule. Finally, the Exchange proposes to renumber existing subparagraph (C)(4) to subparagraph (C)(3) and update the cross cites therein to ''paragraphs (C)(1)–(C)(3)'' to ''subparagraphs (C)(1)–(C)(2).'' [25]

Reference Price

As proposed, the Reference Price used would continue to be based on last sale and would be memorialized in proposed subparagraph (D). Continuing to use the last sale as the Reference Price is necessary for operational efficiency as it may not be possible to perform a timely clearly erroneous review if doing so required computing the arithmetic mean price of eligible reported transactions over the past five minutes, as contemplated by the LULD Plan. While this means that there would still be some differences between the Price Bands and the clearly erroneous parameters, the Exchange believes that this difference is reasonable in light of the need to ensure timely review if clearly erroneous rules are invoked. The Exchange also proposes to allow for an alternate Reference Price to be used as prescribed in proposed subparagraphs (D)(1), (2), and (3). Specifically, the Reference Price may be a value other than the consolidated last sale immediately prior to the execution(s) under review (1) in the case of Multi-Stock Events involving twenty or more securities, as described in subparagraph (C)(2)(ii) above, (2) in the case of an erroneous Reference Price, as described in subparagraph (C)(1)(iii) above,[26] or (3) in other circumstances, such as, for example, relevant news impacting a security or securities, periods of extreme market volatility, sustained illiquidity, or widespread system issues, where use of a different Reference Price is necessary for the maintenance of a fair and orderly market and the protection of investors and the public interest, provided that such circumstances occurred during Pre-Market or Post-Market Hours or are eligible for review pursuant to subparagraph (C)(1)(i).

System Disruption or Malfunction

To conform with the structural changes described above, the Exchange now proposes to remove paragraph (b)(i), System Disruption or Malfunctions, and renumber existing paragraph (b)(ii) as (b)(i). Additionally, the Exchange proposes to add rule text in renumbered (b)(i) (Senior Official Acting on Own Motion) to specify that a Senior Official, acting on his or her own motion, may review potentially erroneous transactions that occur only during Pre-Market or Post-Market Hours or that are eligible for review pursuant to proposed paragraph (a)(2)(C)(1).

The Exchange also proposes new subparagraph (C)(1)(ii) of Rule 11890(a)(2). Specifically, as described in subparagraph (C)(1)(ii), transactions occurring during Market Hours that are executed outside of the LULD Price Bands due to an Exchange technology or system issue, may be subject to clearly erroneous review pursuant to proposed paragraph (g) of Rule 11890. Proposed subparagraph (C)(1)(ii) further provides that a transaction subject to review pursuant to this paragraph shall be found to be clearly erroneous if the price of the transaction to buy (sell) that is the subject of the complaint is greater than (less than) the Reference Price, described in subparagraph (D), by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan.

Securities Subject to Limit Up-Limit Down Plan

The Exchange proposes to rename paragraph (g) (Securities Subject to LULD Plan) as ''Transactions Occurring Outside of LULD Price Bands.'' Given that proposed subparagraph (C)(1) of Rule 11890(a)(2) defines the LULD Plan, the Exchange also proposes to eliminate redundant language from paragraph (g). Finally, the Exchange also proposes to update references to the LULD Plan and Price Bands so that they are uniform throughout the Rule and to update rule references throughout the paragraph to conform to the structural changes to the Rule described above.

Fees, Multi-Day Event and Trading Halts

The Exchange proposes to modify the text of paragraphs (e) (Fees), (h) (Multi-Day Event), and (i) (Trading Halts) to reference the Percentage Parameters as well as the Numerical Guidelines, and

[25] The Exchange will make a related change to update the cross cite within current paragraph (b)(ii).

[26] As discussed above, in the case of (C)(1)(iii)(1), the Exchange would consider a number of factors to determine a new Reference Price that is based on the theoretical value of the security, including but not limited to, the offering price of the new issue, the ratio of the stock split applied to the prior day's closing price, the theoretical price derived from the numerical terms of the corporate action transaction such as the exchange ratio and spin-off terms, and the prior day's closing price on the OTC market for an OTC up-listing. In the case of (C)(1)(iii)(2), the Reference Price will be the last effective Price Band that was in a limit state before the Trading Pause.

to update rule references therein to conform to the structural changes to the Rule described above. Specifically, the existing text of paragraph (e) provides that adjustments or voluntary breaks negotiated by Nasdaq to trades executed at prices that meet the Numerical Guidelines set forth in (a)(2)(C)(1) count as breaks by Nasdaq for purposes of this paragraph. The Exchange now proposes to amend the rule text to state that adjustments or voluntary breaks negotiated by Nasdaq to trades executed at prices that meet the Percentage Parameters or Numerical Guidelines set forth in (a)(2)(C)(2) count as breaks by Nasdaq for purposes of this paragraph.

In addition, the existing text of paragraphs (h) and (i) provides that any action taken in connection with this paragraph will be taken without regard to the Numerical Guidelines set forth in this Rule. The Exchange proposes to amend the rule text to provide that any action taken in connection with this paragraph will be taken without regard to the Percentage Parameters or Numerical Guidelines set forth in this Rule, with the Percentage Parameters being applicable to an NMS Stock subject to the LULD Plan and the Numerical Guidelines being applicable to an NMS Stock not subject to the LULD Plan.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[27] in general, and Section 6(b)(5) of the Act,[28] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

As explained in the purpose section of this proposed rule change, the current pilot was implemented following the Flash Crash to bring greater transparency to the process for conducting clearly erroneous reviews, and to help assure that the review process is based on clear, objective, and consistent rules across the U.S. equities markets. The Exchange believes that the amended clearly erroneous rules have been successful in that regard and have thus furthered fair and orderly markets. Specifically, the Exchange believes that the pilot has successfully ensured that such reviews are conducted based on objective and consistent standards across SROs and has therefore afforded greater certainty to Members and investors. The Exchange therefore believes that making the current pilot a permanent program is appropriate so that equities market participants can continue to reap the benefits of a clear, objective, and transparent process for conducting clearly erroneous reviews. In addition, the Exchange understands that the other U.S. equities exchanges and FINRA will also file largely identical proposals to make their respective clearly erroneous pilots permanent. The Exchange therefore believes that the proposed rule change would promote transparency and uniformity across markets concerning review of transactions as clearly erroneous and would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors, and the public interest.

Similarly, the Exchange believes that it is consistent with just and equitable principles of trade to limit the availability of clearly erroneous review during Market Hours. The LULD Plan was approved by the Commission to operate on a permanent rather than pilot basis. As a number of market participants have noted, the LULD Plan provides protections that ensure that investors' orders are not executed at prices that may be considered clearly erroneous. Further, amendments to the LULD Plan approved in Amendment Eighteen serve to ensure that the Price Bands established by the LULD Plan are ''appropriately tailored to prevent trades that are so far from current market prices that they would be viewed as having been executed in error.'' [29] Thus, the Exchange believes that clearly erroneous review should only be necessary in very limited circumstances during Market Hours. Specifically, such review would only be necessary in instances where a transaction was not subject to the LULD Plan, or was the result of some form of systems issue, as detailed in the purpose section of this proposed rule change. Additionally, in narrow circumstances where the transaction was subject to the LULD Plan, a clearly erroneous review would be available in the case of (1) a corporate action or new issue or (2) a security that enters a Trading Pause pursuant to LULD and resumes trading without an auction, where the Reference Price is determined to be erroneous by an Officer of the Exchange or senior level employee designee because it clearly deviated from the theoretical value of the security. Thus, eliminating clearly erroneous review in all other instances will serve to increase certainty for Members and investors that trades executed during Market Hours would typically stand and would not be subject to review.

Given the fact that clearly erroneous review would largely be limited to transactions that were not subject to the LULD Plan, the Exchange also believes that it is necessary to change the parameters used to determine whether a trade is clearly erroneous. Specifically, due to the different parameters currently used for clearly erroneous review and for determining Price Bands, it is possible that a trade that would have been permitted to execute within the Price Bands would later be deemed clearly erroneous, if, for example, a systems issue prevented the dissemination of the Price Bands. The Exchange believes that this result is contrary to the principle that trades within the Price Bands should stand, and has the potential to cause investor confusion if trades that are properly executed within the applicable parameters described in the LULD Plan are later deemed erroneous. By using consistent parameters for clearly erroneous reviews conducted during Market Hours and the calculation of the Price Bands, the Exchange believes that this change would also serve to promote greater certainty with regards to when trades may be deemed erroneous.

Finally, the proposed rule changes make organizational updates to Rule 11890 as well as minor updates and corrections to the Rule to improve readability and clarity.

B. Self-Regulatory Organization's Statement on Burden on Competition

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. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while also amending those rules to provide greater certainty to Members and investors that trades will stand if executed during Market Hours where the LULD Plan provides adequate protection against trading at erroneous prices. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to this proposal. Thus, the proposed rule change will help to ensure consistency

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

[29] *See* Amendment Eighteen, *supra* note 6.

across SROs without implicating any competitive issues.

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)(iii) of the Act [30] and subparagraph (f)(6) of Rule 19b–4 thereunder.[31]

A proposed rule change filed under Rule 19b–4(f)(6) [32] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [33] 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 asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative on October 1, 2022. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Exchange to coordinate its implementation of the revised clearly erroneous execution rules with the other national securities exchanges and FINRA, and will help ensure consistency across the SROs.[34] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[35]

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–052 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–2022–052. 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 (*http://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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–052 and should be submitted on or before October 20, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21068 Filed 9–28–22; 8:45 am]

BILLING CODE 8011–01–P

[30] 15 U.S.C. 78s(b)(3)(A)(iii).

[31] 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 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.

[32] 17 CFR 240.19b–4(f)(6).

[33] 17 CFR 240.19b–4(f)(6)(iii).

[34] *See* SR–CboeBZX–2022–37 (July 8, 2022).

[35] 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).

[36] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17640 and #17641; PUERTO RICO Disaster Number PR–00042]

Presidential Declaration of a Major Disaster for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the Commonwealth of Puerto Rico (FEMA–4671–DR), dated 09/21/2022.

Incident: Hurricane Fiona.

Incident Period: 09/17/2022 and continuing.

DATES: Issued on 09/21/2022.

Physical Loan Application Deadline Date: 11/21/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/21/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/21/2022, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Municipalities (Physical Damage and Economic Injury Loans):

Adjuntas, Aguas Buenas, Aibonito, Arroyo, Barranquitas, Bayamon, Caguas, Canovanas, Carolina,

Catano, Cayey, Ceiba, Ciales, Cidra, Coamo, Comerio, Corozal, Dorado, Fajardo, Florida, Guayama, Guayanilla, Guaynabo, Gurabo, Humacao, Jayuya, Juana Diaz, Juncos, Lares, Las Piedras, Luquillo, Maricao, Maunabo, Morovis, Naguabo, Naranjito, Orocovis, Patillas, Penuelas, Ponce, Rio Grande, Salinas, San Juan, San Lorenzo, Santa Isabel, Toa Alta, Toa Baja, Trujillo Alto, Utuado, Vega Alta, Vega Baja, Vieques, Villalba, Yabucoa, Yauco.

Contiguous Municipalities (Economic Injury Loans Only):

Puerto Rico Arecibo, Barceloneta, Camuy, Guanica, Hatillo, Las Marias, Loiza, Manati, Mayaguez, Sabana Grande, San German, San Sebastian.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.375
Homeowners without Credit Available Elsewhere	2.188
Businesses with Credit Available Elsewhere	6.080
Businesses without Credit Available Elsewhere	3.040
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.040
Non-Profit Organizations without Credit Available Elsewhere 1.875.	

The number assigned to this disaster for physical damage is 17640 8 and for economic injury is 17641 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21106 Filed 9–28–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17638 and #17639; OKLAHOMA Disaster Number OK–00161]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Muscogee (Creek) Nation

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Muscogee (Creek) Nation (FEMA–4670–DR), dated 09/20/2022.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/02/2022 through 05/08/2022.

DATES: Issued on 09/20/2022.

Physical Loan Application Deadline Date: 11/21/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/20/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/20/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area:

Muscogee (Creek) Nation.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17638 C and for economic injury is 17639 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21107 Filed 9–28–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17640 and #17641; Puerto Rico Disaster Number PR–00042]

Presidential Declaration Amendment of a Major Disaster for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Commonwealth of Puerto Rico (FEMA–4671–DR), dated 09/21/2022.

Incident: Hurricane Fiona.

Incident Period: 09/17/2022 and continuing.

DATES: Issued on 09/22/2022.

Physical Loan Application Deadline Date: 11/21/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/21/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Puerto Rico, dated 09/21/2022, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Municipalities (Physical Damage and Economic Injury Loans): Anasco, Hormigueros, Mayaguez.

Contiguous Municipalities (Economic Injury Loans Only):

Puerto Rico: Aguada, Cabo Rojo, Moca, Rincon.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21157 Filed 9–28–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 11873]

Foreign Affairs Policy Board Meeting Notice; Closed Meeting

In accordance with the Federal Advisory Committee Act, 5 U.S.C. app.,

the Department of State announces a meeting of the Foreign Affairs Policy Board to take place on October 12, 2022, at the Department of State, Washington, DC.

The Foreign Affairs Policy Board reviews and assesses: (1) Economic trends with implications for the United States' role abroad (2) diplomatic priorities on cyberspace, digital infrastructure and emerging technologies; (3) the transition to the green and blue economies, and what are the implications for U.S. foreign policy; and (4) preventing the next pandemics and strengthening global health security. Pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. app 10(d), and 5 U.S.C. 552b(c)(1), it has been determined that this meeting will be closed to the public as the Board will be reviewing and discussing matters properly classified in accordance with Executive Order 13526.

This announcement might appear in the **Federal Register** less than 15 days prior to the meeting. The Department of State finds that there is an exceptional circumstance in that this advisory committee meeting must be held on October 12, 2022, due to the requirements of the Secretary of State's schedule. The Secretary intends to brief the Board and engage in a discussion with them at this meeting.

Authority: 22 U.S.C. 2656 and 5 U.S.C. appendix.

For more information, contact Timothy Peltier at (202) 647–2236.

Timothy Peltier,

Designated Federal Officer, Office of Policy Planning, Department of State.

[FR Doc. 2022–21046 Filed 9–28–22; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 11872]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: ''Picasso Ingres: Face to Face'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary display in the exhibition ''Picasso Ingres: Face to Face'' at the Norton Simon Museum of Art, Pasadena, California, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–21123 Filed 9–28–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intentt To Prepare an Environmental Impact Statement, Initiate Section 106 Consultation, and Request for Scoping Comments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement, initiate section 106 consultation, and request scoping comments for the Proposed Airfield, Safety, and Terminal Improvement Project at West Virginia International Yeager Airport, Charleston, Kanawha County, West Virginia.

SUMMARY: The Federal Aviation Administration (FAA) is issuing this notice under the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended, to advise the public that an Environmental Impact Statement (EIS) will be prepared to assess the potential impacts of the proposed Airfield, Safety, and Terminal Improvement Project and its connected actions (the Proposed Action) at the West Virginia International Yeager Airport (CRW or Airport). The Central West Virginia Regional Airport Authority (CWVRAA) is proposing to develop the project in phases to address various safety and operational deficiencies at the Airport. The immediate need is to improve the runway safety areas, meet existing runway length requirements for the Airport's runway, and replace aging and inefficient infrastructure in the terminal area. Phase 1 of CWVRAA's proposed development is intended to address these immediate needs. The long-term need is dependent on and in support of a potential change in the aircraft serving CRW and/or forecast destinations that are anticipated to occur by 2040. Phase 2 of CWVRAA's proposed development is intended to address these long-term needs. To ensure that all significant issues related to the Proposed Action are identified, two (2) in-person public scoping meetings, one (1) virtual public scoping meeting, and one (1) governmental agency scoping meeting will be held.

DATES: The effective date of start of FAA's EIS scoping period is September 30, 2022. The public and agency scoping comment period ends November 17, 2022. In-person public meetings will be held on November 2, 2022 and November 3, 2022. A virtual public meeting will be held November 7, 2022. A governmental agency scoping meeting will be held November 3, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Brooks, Environmental Program Manager, Eastern Regional Office, AEA–610, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, NY 11434. Telephone: 718–553–2511.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to inform federal, state, and local government agencies and the public of the intent to prepare an EIS, to initiate the public and agency scoping process for the EIS, and to conduct public and agency scoping meetings. The purpose of the scoping process is to receive input from the public, as well as from federal, state, and local agencies that have legal jurisdiction and/or special expertise, with respect to any potential environmental impacts associated with the Proposed Action, as well as concerns, issues, and alternatives they believe should be addressed in the EIS. During the scoping process, questions regarding the scope and EIS process will be considered. More information about the Proposed Action, the EIS process, and the scoping meetings can be found at: *www.yeagerairporteis.com*.

The scoping process for this EIS will include scoping meetings and a

comment period for interested agencies and members of the public to submit comments with respect to any potential environmental impacts associated with the Proposed Action, or comments representing the concerns, issues, and alternatives they believe should be addressed in the EIS. The public scoping meetings will provide the opportunity to provide written and/or oral comments. Additional written comments should be submitted to the FAA individual listed in **FOR FURTHER INFORMATION CONTACT**, or by email to *comments@yeagerairporteis.com,* no later than 5 p.m. eastern time, Monday, November 17, 2022.

The EIS will be prepared in accordance with the procedures described in the most recent version of applicable FAA orders and guidance, such as FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* and FAA Order 5050.4B, *National Environmental Policy Act (NEPA) Implementing Instructions for Airport Actions*. The FAA intends to use the preparation of this EIS to comply with the concurrent statutory review process under section 106 of the National Historic Preservation Act (NHPA); section 4(f) of the Department of Transportation (DOT) Act; section 6(f) of the Land and Water Conservation Fund (LWCF) Act; section 7 of the Endangered Species Act; the Magnuson-Stevens Fishery Conservation and Management Act; section 10 of the Rivers and Harbors Act; and section 401 and section 404 of the Clean Water Act. This notice of intent also serves to satisfy the public notice and comment requirements of section 106 of the NHPA; section 4(f) of the DOT Act; section 6(f) of the LWCF Act; DOT Order 5610.2C, *U.S. Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*; Executive Order 11990, *Protection of Wetlands*; DOT Order 5660.1A, *Preservation of the Nation's Wetlands*; Executive Order 11988, *Floodplain Management*; and DOT Order 5650.2, *Floodplain Management and Protection*.

The Proposed Action would require a number of approvals from other federal, state, and local agencies. As the NEPA lead federal agency for the Proposed Action, the FAA invited several agencies to be a Cooperating or Participating Agency in the development of the EIS (40 CFR 1501.8, 1508.1(e), and 1508.1(w)). Cooperating Agencies for the EIS include US Army Corps of Engineers, US Environmental Protection Agency, West Virginia Department of Environmental Protection, West Virginia Development Office, and Kanawha County Parks and Recreation Commission. Participating Agencies for the EIS include Federal Emergency Management Agency, National Park Service, West Virginia Air National Guard, West Virginia Division of Natural Resources, West Virginia State Historic Preservation Office, Kanawha County Department of Planning and Development, Kanawha County Commission, and City of Charleston Planning Department. Additional agencies may be identified throughout the EIS process.

The Proposed Action, as put forward by the CWVRAA, the owner and operator of CRW, would include the shift and extension of Runway 5–23 to the northeast (Runway 23 approach end), construction of a new terminal complex, relocation of Taxiway A and portions of Taxiway B, and connected actions and enabling projects to support the Proposed Action. To separately satisfy immediate and long-term needs of the Airport, the Proposed Project would be developed in two separate phases.

Phase 1 of the Proposed Action would include the following components:

- shift the runway to the northeast by 1,125 feet and extend it by 285 feet, resulting in a total runway length of 7,000 feet;
- construction of standard 1,000-foot by 500-foot graded Runway Safety Areas (RSAs) on both ends of the runway;
- extension of Taxiway A parallel to the new portion of the runway at a standard 400-foot separation distance;
- construction of new entrance, exit, and connector taxiways to connect Taxiway A to the runway shift and extension;
- relocation of associated runway navigational aids (NAVAIDS);
- relocation of portions of the airport operation area (AOA) perimeter fence;
- construction of new vehicle service roads;
- demolition or marking as unusable existing airfield pavement;
- relocation of portions of Taxiway A, from the existing end of Runway 5 to Taxiway C;
- relocation of Taxiway B, extending from Taxiway A to Taxiway Connector B5;
- construction of a 166,000-square-foot replacement terminal, including a replacement concourse, with six total aircraft gates. The replacement terminal would comprise three levels and would include two pedestrian walkway systems, one connecting the replacement terminal to the rental car center/garage and one connecting the replacement terminal to the existing parking garage;
- demolition of the existing terminal facility including existing aircraft gates;
- construction of new apron pavement for the replacement terminal;
- construction of terminal roadway improvements, including a new roundabout at the airport entrance road to support reoriented entrance and exits from the parking areas, and construction of pavement to support a new truck loading dock;
- property acquisition of portions of Coonskin Park for the runway shift and extension;
- identification of replacement properties for Coonskin Park in accordance with section 6(f) of the LWCF Act;
- use of up to approximately 25.6 million cubic yards of fill, potentially utilized from borrow areas located in the adjacent Coonskin Park, necessary to fill in the valley floor for which the extended runway would be constructed and to remove terrain obstructions;
- use of up to approximately 60,000 cubic yards of fill to support the proposed terminal facility and apron expansion;
- construction of three retaining walls and a culvert for Coonskin Branch to facilitate the proposed fill material;
- removal of Coonskin Park facilities within the cut/fill areas; and
- new and relocated utilities to support construction of the Proposed Action.

Phase 2 of the Proposed Action would include the following components:

- shift the runway to the northeast by an additional 280 feet and extend it by an additional 1,000 feet to the northeast (along the existing alignment), resulting in a total runway length of 8,000 feet;
- construction of standard 1,000-foot by 500-foot graded RSAs on both ends of the runway;
- extension of Taxiway A parallel to the new portion of the runway at a standard 400-foot separation distance;
- construction of new entrance, exit, and connector taxiways to connect Taxiway A to the runway shift and extension;
- relocation of associated runway NAVAIDS and installation of an approach lighting system for Runway 5;
- relocation of portions of the AOA perimeter fence;
- construction of new vehicle service roads;
- demolition or marking as unusable existing airfield pavement;
- relocation of the remaining portion of Taxiway A between Taxiway C and the existing Runway 23 end to the standard 400-foot runway to taxiway centerline separation distance;

• construction of a seventh gate to the replacement terminal facility;
• use of up to approximately 4 million cubic yards of fill, potentially utilized from borrow areas located in the adjacent Coonskin Park, and construction of a retaining wall, to support the relocation of Taxiway A; and
• potential relocation of the Airport Traffic Control Tower (ATCT).

The FAA will consider a range of alternatives that could potentially meet the purpose and need to enhance airfield safety, meet existing and forecast future runway needs, and improve efficiency in the terminal area at CRW. As part of the information submittal process, the CWVRAA provided an initial list of alternatives that they had considered. These alternatives, as well as additional identified alternatives, are included below. After considering the public and agency scoping process input, the FAA will identify a list of reasonable alternatives that will be evaluated through the EIS process.

Runway Length of 6,715 Feet: Provide standard runway safety areas or standard EMAS on either or both ends of the runway considering the current physical runway length is 6,715 feet. These alternatives could result in shifting the existing runway.

Runway Length of 6,802 Feet: Provide standard runway safety areas or standard EMAS on either or both ends of the runway considering the previous (pre-slope failure) runway length of 6,802 feet. These alternatives could result in extending and/or shifting the existing runway.

Runway Length of 7,000 Feet: Provide standard runway safety areas or standard EMAS on either or both ends of the runway considering a runway length of 7,000 feet. These alternatives could result in extending and/or shifting the existing runway.

Runway Length of 8,000 Feet: Provide standard runway safety areas or standard EMAS on either or both ends of the runway considering a runway length of 8,000 feet. These alternatives could result in extending and/or shifting the existing runway.

Replacement Terminal: Construct a replacement terminal in a location and manner that improves the efficiency of both airfield and terminal building operations. These alternatives would identify various locations at the Airport for a replacement terminal.

Construction of a New Airport: Construction of a new airport designed to meet all FAA standards.

Transfer of Aviation Activity to Other Airports: Transfer or shifting of aviation activity to another existing public airport (or airports) in West Virginia.

Use of Other Modes of Transportation: Use of other modes of transportation, including automobiles, buses, or existing passenger trains.

No Action Alternative: Under this alternative, the existing airport would remain unchanged. The Authority would take no action to enhance airfield safety, improve Airport operations to meet the takeoff runway length needs, or improve passenger efficiency or experience within the terminal area.

Public Scoping and Agency Meetings

To ensure that the full range of issues related to the Proposed Action are addressed and that all significant issues are identified, comments and suggestions are invited from all interested parties. Public and agency scoping meetings will be conducted to identify any significant issues associated with the Proposed Action.

A governmental agency scoping meeting for all federal, state, and local regulatory agencies which have jurisdiction by law or have special expertise with respect to any potential environmental impacts associated with the Proposed Action will be held on Thursday, November 3, 2022. This meeting will take place at 1 p.m. eastern time, at the Embassy Suites by Hilton Charleston Hotel located at 300 Court Street, Charleston, West Virginia, and will be available virtually via Zoom with a dial-in number to participate via web/telephone, if preferred. A notification letter will be sent in advance of the meeting.

Three public scoping meetings for the general public will be held. The two in-person public scoping meetings will be held from 6 p.m. to 8 p.m. eastern time on Wednesday, November 2, 2022, and from 6 p.m. to 8 p.m. eastern time on Thursday, November 3, 2022. The public scoping meetings will be conducted at the Embassy Suites by Hilton Charleston Hotel located at 300 Court Street, Charleston, West Virginia. A legal notice will also be placed in newspapers having general circulation in the study area. The newspaper notice will notify the public that scoping meetings will be held to gain their input concerning the Proposed Action, alternatives to be considered, and impacts to be evaluated. The in-person public scoping meetings will be open house format with project information displayed and representatives from the FAA and the CWVRAA available to answer questions. There will be no admission fee or other charge, including parking, to attend and participate.

A virtual public workshop will also be held from 6 p.m. to 8 p.m. on Monday, November 7, 2022. The virtual public workshop will be held via Zoom and will provide the opportunity for interested members of the public to participate in a question-and-answer session with representatives from the FAA and the CWVRAA. Registration is required for the virtual public workshop, which is available on the project website at *www.yeagerairporteis.com*. Translation services, including sign language interpretation, can be made available during the public meetings and workshop, if requested 10 calendar days before the sessions.

Written and oral comments will be accepted at each of the meetings. Comments submitted outside of the meetings should be addressed to the individual listed in **FOR FURTHER INFORMATION CONTACT**, or by email to *comments@yeagerairporteis.com*. The Scoping comment period is from September 30, 2022, through November 17, 2022. The public comment period on the scoping phase of the EIS will end at 5 p.m. eastern time on November 17, 2022.

The FAA is aware that there are Native American tribes with a historical interest in the area. The FAA is interacting with them on a government-to-government basis, in accordance with all executive orders, laws, regulations, and other memoranda. The tribes have also been invited to participate in accordance with NEPA, section 106 of the NHPA, and FAA Order 1210.20, *American Indian and Alaska Native Tribal Consultation Policy and Procedures*.

Issued in Beaver, West Virginia, September 26, 2022.

Matthew Digiulian,

Manager, Beckley Airport Field Office, Airports Division, Eastern Region.

[FR Doc. 2022–21162 Filed 9–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2022–1202]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Reduction of Fuel Tank Flammability on Transport Category Airplanes

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 a previously approved information collection. The FAA's Fuel Tank Flammability Safety rule requires manufacturers to report to the FAA every 6 months on the reliability of the fuel tank flammability reduction systems of their fleet. The data is needed to assure system performance meets that predicted at the time of certification. This collection of information supports the Department of Transportation's strategic goal of safety.

DATES: Written comments should be submitted by November 28, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: https://www.regulations.gov (Enter docket number into search field).

By mail: Monica Caldwell, FAA National Headquarters, 800 Independence Ave. SW, Washington, DC 20591–0001.

By fax: 405–225–2350.

FOR FURTHER INFORMATION CONTACT: Philip Dang by email at: *Philip.M.Dang@faa.gov;* phone: 206–231–3442.

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. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0710.

Title: Reduction of Fuel Tank Flammability on Transport Category Airplanes.

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 September 19, 2019 (84 FR 49174). There were no comments. Design approval holders use flammability analysis documentation to demonstrate to their FAA Oversight Office that they are compliant with the Fuel Tank Flammability Safety rule (73 FR 42443). Semi-annual reports submitted by design approval holders provide listings of component failures discovered during scheduled or unscheduled maintenance so that the reliability of the flammability reduction means can be verified by the FAA.

Respondents: Approximately nine design approval holders.

Frequency: Every three years.

Estimated Average Burden per Response: Minutes/Hours 100 hours.

Estimated Total Annual Burden: 1,800 hours.

Issued in Kansas City, Missouri on September 26, 2022.

Patrick R. Mullen,

Technical Innovation Policy Branch Manager, Policy and Innovation, Aircraft Certification Service.

[FR Doc. 2022–21166 Filed 9–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Potential Federal Insurance Response to Catastrophic Cyber Incidents

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Request for comment.

SUMMARY: Over the past several years, the Federal Insurance Office (FIO) in the U.S. Department of the Treasury (Treasury) has continued its ongoing efforts with regard to both cyber insurance and insurer cybersecurity. Cyber insurance is a significant risk-transfer mechanism, and the insurance industry has an important role to play in strengthening cyber hygiene and building resiliency. FIO has also increased its data collection in this area with regard to the Terrorism Risk Insurance Program (TRIP) and has supported the development of Treasury's counter-ransomware strategy. The Government Accountability Office (GAO) released a report in June 2022 recommending that FIO and the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA) conduct a joint assessment to determine ''the extent to which risks to critical infrastructure from catastrophic cyber incidents and potential financial exposures warrant a federal insurance response.'' Both FIO and CISA have agreed to conduct the recommended assessment. FIO is also coordinating with the White House Office of the National Cyber Director on these issues.

In order to inform FIO's future work and the joint assessment, FIO is seeking comments from the public on questions related to cyber insurance and catastrophic cyber incidents.

DATES: Submit comments on or before. November 14, 2022.

ADDRESSES: Submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site, or by mail to the Federal Insurance Office, Attn: Richard Ifft, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220. Because postal mail may be subject to processing delays, it is recommended that comments be submitted electronically. If submitting comments by mail, please submit an original version with two copies. Comments should be captioned with ''Potential Federal Insurance Response to Catastrophic Cyber Incidents.'' In general, Treasury will post all comments to *www.regulations.gov* without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. All comments, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly. Where appropriate, a comment should include a short Executive Summary (no more than five single-spaced pages).

Additional Instructions. Responses should also include: (1) the data or rationale, including examples, supporting any opinions or conclusions; and (2) any specific legislative, administrative, or regulatory proposals for carrying out recommended approaches or options.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, (202) 622–2922, *Richard.Ifft@treasury.gov,* Jeremiah Pam, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, (202) 622–7009, *Jeremiah.Pam2@treasury.gov,* or Philip Goodman, Senior Insurance Regulatory Policy Analyst (202) 622–1170, *Philip.Goodman@treasury.gov.* Persons who have difficulty hearing or speaking may access these numbers via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Cyber insurance is an increasingly significant risk-transfer mechanism, and the insurance industry has an important

role to play in strengthening cyber hygiene and building resiliency.[1] Through underwriting and pricing, insurers can encourage or even require policyholders to implement strong cybersecurity standards and controls. More generally, cyber insurance ''can help policyholders respond to lawsuits and loss, and provide associated mitigation services, arising in a variety of situations such as data loss, cloud outage, distributed denial-of-service attacks, malware, and associated ransomware extortion.'' [2] Cyber insurance is a growing market, with approximately $4 billion in direct premiums written in 2020.[3]

On June 21, 2022, GAO issued a report, *Cyber Insurance: Action Needed to Assess Potential Federal Response to Catastrophic Attacks* (GAO Report).[4] The GAO Report emphasizes three points about the catastrophic risk of cyber incidents. First, cyber incidents impacting critical infrastructure have increased in frequency and severity. The GAO Report cites a 2020 study by CISA that includes an analysis of scenario-based estimates of potential losses from severe cyber incidents that ranged from $2.8 billion to $1 trillion per event for the United States.[5] Second, the GAO Report finds that recent attacks demonstrate the potential for systemic cyber incidents, citing recent cyber attacks that ''illustrate that the effects of cyber incidents can spill over from the initial target to economically linked firms—thereby magnifying the damage to the economy.'' [6] Third, the GAO Report evaluates some of the issues regarding potential risks presented by cyber incidents to critical infrastructure in the United States.[7] (Market participants, including insurers and reinsurers, have similarly highlighted the risks presented by catastrophic and/or systemic cyber incidents with regard to the cyber insurance market.[8]) The GAO Report also identified potential issues in creating a federal insurance cyber backstop within the scope of the Terrorism Risk Insurance Program (TRIP).[9]

The GAO Report concludes that a full evaluation of whether there should be a federal insurance response in connection with catastrophic cyber risks would be best addressed by FIO (given its statutory authorities, including monitoring of the insurance sector and assisting the Secretary of the Treasury with administration of TRIP) and CISA (given its expertise in connection with cyber and physical risks to U.S. infrastructure) in a joint assessment to be provided to Congress.[10] Both FIO and CISA accepted the GAO recommendation to conduct such a joint assessment, as reflected in letters attached to the GAO Report.

As a threshold matter, ''insurance responses'' can take many forms. Most insurance in the United States is provided through private insurance companies that are regulated at the state level. However, there are a large number of programs and mechanisms, both at the state and federal level, where insurance coverage may be provided or mandated by state or federal requirements. These arrangements have typically been put into place when the private market has failed to make available affordable insurance to policyholders. At the state level, many states have created residual market funds that ensure all policyholders can obtain coverage (with those obligations spread across the industry as a whole in some fashion) in areas such as workers' compensation, automobile, and property insurance.[11] There are also several federal programs in this area, including TRIP,[12] the National Flood Insurance Program,[13] the Federal Crop Insurance Program,[14] and others.

FIO, in association with CISA, seeks public comments as to whether a federal insurance response to ''catastrophic'' [15] cyber incidents may be warranted, as well as how such an insurance response should be structured and other related issues. FIO intends to assess potential federal insurance responses that are outside of TRIP, but will also consider how potential responses could interact with, or be part of, TRIP. State and federal governments have responded in a variety of ways to situations in which the private market is unable to provide sufficient or affordable insurance, and FIO seeks input on a wide range of options and potential response structures.

Among other things, FIO is seeking comment on issues concerning the risks of catastrophic cyber incidents to critical infrastructure,[16] the potential

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[1] *See, e.g.,* FIO, *Annual Report on the Insurance Industry* (September 2021), 74–78, *https://home.treasury.gov/system/files/311/FIO-2021-Annual-Report-Insurance-Industry.pdf* (*2021 Annual Report*).

[2] FIO, *2021 Annual Report,* 74.

[3] FIO, *Effectiveness of the Terrorism Risk Insurance Program* (June 2022), 62, *https://home.treasury.gov/system/files/311/2022%20Program%20Effectiveness%20Report%20%28FINAL%29.pdf.*

[4] GAO, *Cyber Insurance: Action Needed to Assess Potential Federal Response to Catastrophic Attacks (2022), https://www.gao.gov/products/gao-22-104256.*

[5] *See* GAO Report, 25 (citing CISA, *Cost of a Cyber Incident: Systematic Review and Cross Validation* (2020), 14, *https://www.cisa.gov/sites/default/files/publications/CISA-OCE_Cost_of_Cyber_Incidents_Study-FINAL_508.pdf*).

[6] *See* GAO Report, 16 (identifying the May 2021 attack on the Colonial Pipeline Company, the July 2021 attack on Kaseya, and the February 2022 attack on Viasat, Inc.).

[7] *See* GAO Report, 9–12.

[8] *See, e.g.,* Chubb, *Catastrophic Cyber Risks—A Growing Concern* (2021), 6, *https://www.chubb.com/content/dam/chubb-sites/chubb-com/us-0en/global/global/documents/pdf/2021-10.21_17-01-0286_Cyber_Systemic_Risks_whitepaper.pdf;* Carnegie Endowment for International Peace, *Systemic Cyber Risk: A Primer* (March 7, 2022), *https://carnegieendowment.org/2022/03/07/systemic-cyber-risk-primer-pub-86531;* Geneva Association and the International Forum of Terrorism Risk (Re)Insurance Pools, *Insuring Hostile Cyber Activity: In search of sustainable solutions* (January 2022), 16–20, *https://www.genevaassociation.org/sites/default/files/research-topics-document-type/pdf_public/cybersolutions_web.pdf.*

[9] The GAO Report was originally mandated in the 2019 reauthorization of the Terrorism Risk Insurance Program, which was enacted as part of the Further Consolidated Appropriations Act, 2020, Public Law 116–94, section 502, 133 Stat. 2534, 3027 (2019). *See* GAO, *Cyber Insurance* (2022), 3. Specifically, the Terrorism Risk Insurance Program Reauthorization Act of 2019 directed GAO to provide Congress with a study and report that shall:

(1) analyze and address—

(A) overall vulnerabilities and potential costs of cyber attacks to the United States public and private infrastructure that could result in physical or digital damage;

(B) whether State-defined cyber liability under a property and casualty line of insurance is adequate coverage for an act of cyber terrorism;

(C) whether such risks can be adequately priced by the private market; and

(D) whether the current risk-share system under the Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) is appropriate for a cyber terrorism event; and

(2) set forth recommendations on how Congress could amend the Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) to meet the next generation of cyber threats.

Public Law 116–94 at sec. 502(d).

[10] GAO Report, 33.

[11] *See* FIO, *Annual Report on the Insurance Industry* (2021), 66–67, *https://home.treasury.gov/system/files/311/FIO-2021-Annual-Report-Insurance-Industry.pdf.*

[12] Terrorism Risk Insurance Act of 2002, Public Law 107–297, 116 Stat. 2322 (2002), as amended, 15 U.S.C. 6701 note. The operation of TRIP is described in FIO's most recent report addressing the effectiveness of the Program. *See* FIO, *The Effectiveness of the Terrorism Risk Insurance Program* (June 2022), 5–8, *https://home.treasury.gov/system/files/311/2022%20Program%20Effectiveness%20Report%20%28FINAL%29.pdf.*

[13] *See generally* ''Flood Insurance,'' FEMA, last updated March 9, 2022, *https://www.fema.gov/flood-insurance.*

[14] *See generally* ''Crop Insurance: Keeps America Growing,'' National Crop Insurance Services, *https://cropinsuranceinamerica.org/.*

[15] FIO also seeks information on possible definitions of what constitutes a ''catastrophic'' cyber incident, but in this context the term is generally related to the magnitude of the loss, its dispersion among multiple entities, and the degree of critical services affected.

[16] As noted above, the GAO Report recommends a joint assessment on the extent to which the risks to the nation's *critical infrastructure* from catastrophic cyber attacks, and the potential financial exposures resulting from these risks, warrant a federal insurance response. CISA has

quantification of such risks, the extent of existing private market insurance protection for such risks, whether a federal insurance response is warranted, and how such a federal insurance response, if warranted, should be structured.

II. Solicitation for Comments

FIO seeks comments on each of the following topics:

Catastrophic Cyber Incidents

1. *Nature of Event.* What type of cyber incidents could have a catastrophic effect on U.S. critical infrastructure? How likely are such incidents? Are particular sectors of U.S. critical infrastructure more susceptible to such incidents? How should the federal government and/or the insurance industry address the potential for cascading, cross-sector impacts from a cyber incident? What type of potential ''catastrophic'' cyber incident could justify the creation of a federal insurance response?

2. *Measuring Financial and Insured Losses.* What data and methodologies could the federal government and/or the insurance industry use to predict, measure and assess the financial impact of catastrophic cyber incidents? What amount of financial losses should be deemed ''catastrophic'' for purposes of any potential federal insurance response? How should FIO measure and assess potential insured loss from catastrophic cyber incidents?

3. *Cybersecurity Measures.* What cybersecurity measures would most effectively reduce the likelihood or magnitude of catastrophic cyber incidents? What steps could the federal government take to potentially incentivize or require policyholders to adopt these measures?

Potential Federal Insurance Response for Catastrophic Cyber Incidents

4. *Insurance Coverage Availability.* What insurance coverage is currently available for catastrophic cyber incidents? What are the current limitations on coverage for catastrophic cyber incidents? What rationales have been (or likely would be) used to deny coverage for catastrophic cyber incidents? Is the private market currently making available insurance for catastrophic cyber incidents that is desired by policyholders, in terms of the limits, the scope of coverage, and the type and size of businesses seeking coverage?

5. *Data and Research.* What data do you collect that you would be willing to share with FIO and/or CISA to consider in their assessment of catastrophic cyber incidents and cyber insurance? What other information regarding catastrophic cyber incidents and cyber insurance should FIO and CISA consider? What data should FIO and/or CISA consider collecting to help inform this assessment and their ongoing work?

6. *Federal Insurance Response.* Is a federal insurance response for catastrophic cyber incidents warranted? Why or why not?

7. *Potential Structures for Federal Insurance Response.* What structures should be considered by FIO and CISA for a potential federal insurance response for catastrophic cyber incidents? In your answer, please address:

- *Potential Models.* Should an existing federal insurance program (*e.g.,* NFIP or TRIP) or other U.S. or international public-private insurance mechanism serve as a model for, or be modified to address, catastrophic cyber incidents?
- *Participation.* If there were a federal insurance response, should all cyber insurers be required to participate? Should there be other conditions surrounding participation, whether for cyber insurance or policyholders?
- *Scope of Coverage.* What should be included in the scope of coverage? For example, should it be limited to certain critical infrastructure sectors, size(s) of policyholder permitted to participate, policyholder retentions or deductibles, any required coverages, limits, deductibles, etc.? Should coverage be limited to or differentiate whether a firm is U.S.-based or the infrastructure is located within the U.S.?
- *Cybersecurity Measures.* Should cybersecurity and/or cyber hygiene measures be required of policyholders under the structure? If so, which measures should be required?
- *Moral Hazard.* What measures should be included to minimize potential moral hazard risks (*e.g.,* the possibility that either insurers or policyholders might take undue risks in reliance upon a federal insurance response or fail to implement cybersecurity controls)?
- *Risk Sharing.* How should any structure involving private insurance address risk sharing with the government and the private insurance sector?
- *Reinsurance/Capital Markets.* To what extent should reinsurance arrangements, including capital markets participation, be included in any potential insurance response? How would a potential federal insurance response affect the reinsurance and capital markets?
- *Funding.* How should the structure be funded (*e.g.,* should it be pre- or post-funded)? What might the costs be to the federal government and thus the potential impact on taxpayers?
- *Evaluation/Data Collection.* How should any structure and its program administration be evaluated on an ongoing basis, whether by policymakers and/or administrators, including whether there should be reporting requirements to Congress or other authorities (and on what topics) and data collection (and which information to collect)?
- *Limitations.* What catastrophic risk exposures might insurers be unwilling to insure even if a federal insurance response supporting such coverage were adopted? Should limitations exist between cyber and physical incidents (*e.g.,* causes or impacts)?

8. *Effects on Cyber Insurance Market.* How might a federal insurance response affect the availability and affordability of cyber insurance across the entire insurance market? What would be the effect on any part of the cyber insurance market that would remain outside the parameters of a federal insurance response?

Other

9. Please provide any additional comments or information on any other issues or topics relating to cyber insurance and catastrophic cyber incidents.

Steven E. Seitz,

Director, Federal Insurance Office.

[FR Doc. 2022–21133 Filed 9–28–22; 8:45 am]

BILLING CODE 4810–AK–P

previously identified those critical infrastructure sectors whose ''assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof.'' CISA, ''Critical Infrastructure Sectors,'' *https://www.cisa.gov/critical-infrastructure-sectors.* FIO also seeks comment (see Question 8, below) about the potential effects of a federal insurance response that distinguishes between risks to critical infrastructure and non-critical infrastructure.

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury 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. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before October 31, 2022 to be assured of consideration.

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. Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: Enhanced Oil Recovery Credit

OMB Number: 1545–1292.

Form Number: 8830.

Abstract: This regulation provides guidance concerning the costs subject to the enhanced oil recovery credit, the circumstances under which the credit is available, and procedures for certifying to the Internal Revenue Service that a project meets the requirements of section 43(c) of the Internal Revenue Code.

Current Actions: There are no changes being made to the regulations, at this time. Form 8830 was not issued for 2019–2020 because the section 43 credit was completely phased out and the form was not needed due to the continued high price of crude oil; however, it will apply again for tax years beginning in 2021. The changes made to Form 8830, reflect Notice 2021–47. This will increase the number of responses by 1,550 and annual burden by 11,067 hours.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, and business or other for-profit organizations.

Estimated Number of Respondents: 1,590.

Estimated Time per Respondent: 7.87 hours.

Estimated Total Annual Burden Hours: 12,527.

2. Title: Testimony or Production of Records in a Court or Other Proceeding

OMB Number: 1545–1850.

Regulation Project Number: TD 9178.

Abstract: Final regulation provide specific instructions and to clarify the circumstances under which more specific procedures take precedence. The final regulation extends the application of the regulation to former IRS officers and employees as well as to persons who are or were under contract to the IRS. The final regulation affects current and former IRS officers, employees and contractors, and persons who make requests or demands for disclosure.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals and households, Not-for-Profit institutions, and Farms.

Estimated Number of Respondents: 1,400.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 1,400.

3. Title: Intake/Interview & Quality Review Sheets

OMB Number: 1545–1964.

Form Numbers: 13614–C, 13614–C (AR), 13614–C (BN), 13614–C (BR), 13614–C (DE), 13614–C (FA), 13614–C (FR), 13614–C (GUJ), 13614–C (HT), 13614–C (IT) 13614–C (JA), 13614–C (KM), 13614–C (KO), 13614–C (LP), 13614–C (PA), 13614–C (PL), 13614–C (PT), 13614–C (RU), 13614–C (SO), 13614–C (SP), 13614–C (TL), 13614–C (UR), 13614–C (VIE), 13614–C (ZH–S) 13614–C (ZH–T), and 13614–NR.

Abstract: The Form 13614 series contains a standardized list of required intake questions to guide volunteers in the Tax Counseling for the Elderly (TCE) and Volunteer Income Tax Assistance (VITA) programs in asking taxpayers basic questions about themselves. The form provides the volunteer with structured and consistent information to accurately prepare the taxpayer's return.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 3,750,000.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 625,000.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2022–21158 Filed 9–28–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: National Academic Affiliations Council, Notice of Meeting, Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app. 2, that a meeting of the National Academic Affiliations Council (NAAC) scheduled to be held September 28, 2022–September 29, 2022 at the Orlando VA Health Care System, 13800 Veterans Way, Orlando, FL, 32827 will be converted to a one-day virtual meeting session on September 28, 2022. The amendment resulted in a decision made by VA Leadership in anticipation of the hurricane and in accordance with Federal Emergency Management Agency guidance. Most topics initially scheduled for the two-day meeting agenda will be rescheduled for a future meeting.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On September 28, 2022, the Council will convene an open session from 1:00 p.m. to 3:00 p.m. The agenda will include a presentation on Innovative Academic Relationships: A National Perspective. The Council will also receive updates from the Diversity and Inclusion Subcommittee, the Strategic Academic Advisory Council (SAAC), VA's Electronic Health Record Modernization Work Group related to education and research; and a status update from the Affiliation Partnership Council Subcommittee's Disbursement Workgroup.

Interested persons may attend and/or present oral statements to the Council.

The dial in number to attend the conference call is: 669–254–5252. At the prompt, enter meeting ID 161 228 4971, then press #. The meeting passcode is 101465, then press #. Individuals seeking to present oral statements are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by

the Council prior to the meeting or at any time, by email to *Larissa.Emory@va.gov,* or by mail to Larissa A. Emory PMP, CBP, MS, Designated Federal Officer, Office of Academic Affiliations (14AA), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Ms. Emory via email or by phone at (915) 269–0465.

Dated: September 26, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–21138 Filed 9–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app. 2, that the Executive Committee of the VA Voluntary Service (VAVS) National Advisory Committee (NAC) will meet October 12–13, 2022, at Disabled American Veterans National Service and Legislative Headquarters, 807 Maine Avenue SW, Washington, DC.

Meeting date(s):	Meeting time(s):
Wednesday, October 12, 2022.	9:00 a.m. to 5:00 p.m. Eastern Daylight Time (EDT).
Thursday, October 13, 2022.	9:00 a.m. to 12:30 p.m. EDT.

The meeting sessions open to the public.

The Committee, comprised of 55 major Veteran, civic, and service organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities and strategic partnerships within VA health care facilities, in the community, and on matters related to volunteerism and charitable giving. The Executive Committee consists of 20 representatives from the NAC member organizations.

Agenda topics will include the NAC goals and objectives; review of minutes from the April 27, 2022, Executive Committee meeting; an update on VA Center for Development and Civic Engagement (CDCE) activities; Veterans Health Administration updates; subcommittee reports; review of standard operating procedures; review of fiscal year 2022 organization data; 2023 NAC annual meeting plans; and any new business.

No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review to Dr. Sabrina C. Clark, Designated Federal Officer, VA Center for Development and Civic Engagement (15CDCE), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, or email at *Sabrina.Clark@VA.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Dr. Clark at 202–461–7300.

Dated: September 26, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–21137 Filed 9–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Prosthetics and Special-Disabilities Programs; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (5 U.S.C. App. 2) that a virtual meeting of the Federal Advisory Committee on Prosthetics and Special-Disabilities Programs will be held on Monday, October 25–Tuesday, October 26, 2022. The meeting will be a hybrid meeting, held in-person at VA Central Office, 810 Vermont Avenue NW, Washington, DC, Room 230, and virtually via WebEx. The meeting sessions will begin, and end as follows:

Date:	Time (eastern standard time):
October 25, 2022	9:00 a.m.–3:00 p.m.
October 26, 2022	9:00 a.m.–1:00 p.m.

The virtual meeting sessions are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on VA's prosthetics programs designed to provide state-of-the-art prosthetics and the associated rehabilitation research, development, and evaluation of such technology. The Committee also provides advice to the Secretary on special-disabilities programs, which are defined as any program administered by the Secretary to serve Veterans with spinal cord injuries, blindness or visual impairments, loss of extremities or loss of function, deafness or hearing impairment, and other serious incapacities in terms of daily life functions.

On October 25, 2022, the Committee will convene open (hybrid) sessions on Recreation Therapy and Creative Arts Therapy Service, National Veterans Sports Programs and Special Events, Prosthetic and Sensory Aids Service, Rehabilitation Research and Development Service, and the Office of Integrated Veterans Care.

On October 26, 2022, the Committee members will convene open (hybrid) sessions on Audiology and Speech Pathology Service and Blind Rehabilitation Service.

No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review. Public comments may be received no later than October 17, 2022, for inclusion in the official meeting record. Please send these comments to Dr. Lauren Racoosin, Designated Federal Officer, Rehabilitation and Prosthetic Services, Veterans Health Administration at *Lauren.Racoosin@va.gov.* Members of the public should contact Dr. Lauren Racoosin and provide your name, professional affiliation, email address, and phone number, who wish to obtain a copy of the agenda. Any member of the public wishing to attend or seeking additional information should contact Dr. Racoosin. To attend the meeting, please join the WebEx link below: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m326ad3b10acfa27572452e9d1c6e1401 AudioOnly404.397.1596/ Access Code 2761 980 5183*

Dated: September 23, 2022.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–21073 Filed 9–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity: Veteran Self-Check Assessment (SCA)

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the

proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 28, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Janel Keyes, Office of Regulations, Appeals, and Policy (10BRAP), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Janel.Keyes@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Veteran Self-Check Assessment (SCA).

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: The Veterans Crisis Line (VCL) Chat program allows Veterans, along with their families and friends, to interact online, anonymously, through chat services with a trained VCL Responder. The VCL Chat program is available to all Veterans who may or may not be enrolled in the VA health care system and provides them with online access to the VCL and the VA's suicide prevention services. For many Veterans, their first contact with VHA is through this program. To help facilitate Veterans' utilization of the Chat program and enhance the Chat Responders' ability to understand and respond effectively to Veteran-users, the VCL has implemented the Self-Check Assessment (SCA).

The SCA is an online, confidential, and anonymous risk assessment tool for U.S. Veterans, Active-Duty Service Members (ADSM), members of the National Guard and Reserves or family members of someone in one of those groups. The SCA tool is used to seamlessly link Veterans and their families with the VCL Chat program. At no point is the respondent asked to give their name or any other identifying information. The respondent is assigned a unique identifying number called a ''Reference Code'' that they use to get the VCL Responder's response to their SCA. The participant answers to the SCA are collected, and the program automatically calculates and lists their risk Tier based on their responses. The VCL Responder then reviews the SCA answers and sends a message to the participant, which they receive using their ''Reference Code.'' This messaging encourages the individual to connect to a VCL Responder via an online chat link on the page. The VCL Responder will engage the participant in exploring any service needs they may have and direct them on how they might benefit from VA or community-based services.

Affected Public: Individuals and households.

Estimated Annual Burden: 1,964 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 11,783.

By direction of the Secretary.

Dorothy Glasgow,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–21040 Filed 9–28–22; 8:45 am]

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101
Food Labeling: Nutrient Content Claims; Definition of Term ''Healthy''; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2016–D–2335]

RIN 0910–AI13

Food Labeling: Nutrient Content Claims; Definition of Term ''Healthy''

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans (Dietary Guidelines), regarding how consumers can maintain healthy dietary practices. This action, if finalized, will revise the requirements for when the term ''healthy'' can be used as an implied claim in the labeling of human food products to indicate that a food's level of nutrients may help consumers maintain healthy dietary practices by helping them achieve a total diet that conforms to dietary recommendations.

DATES: Either electronic or written comments on the proposed rule must be submitted by December 28, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by October 31, 2022.

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 December 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2016–D–2335 for ''Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy.' '' 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.'' 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.

Submit comments on information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *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 title of this proposed collection is ''Food Labeling Regulations,'' OMB control number 0910–0381.

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Vincent de Jesus, Center for Food Safety and Applied Nutrition, HFS–830, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450, *vincent.dejesus@fda.hhs.gov;* or Denise See, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: Domini Bean, FDA PRA Staff, 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:

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I. Executive Summary

A. Purpose of the Proposed Rule

Consumers rely on food labels when navigating the marketplace to make informed choices about the foods that are the foundation of a nutritious diet for both themselves and members of their families. FDA plays an important role in ensuring labels of food for human consumption are accurate, truthful, and not misleading, including claims that appear in product labeling to market a food. One such claim that FDA has regulated is the term ''healthy'' on product labels. Since 1994, we have recognized that when a manufacturer uses labeling that describes a product as ''healthy'' in the nutritional context, it is making an implicit claim of the level of nutrients of the product. In particular, such a label implies that the nutrient content of the food may help consumers maintain healthy dietary practices. Given that nutrition science has evolved since the 1990s when FDA first established a definition for the implied nutrient content claim ''healthy,'' the proposed rule would update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance. The proposed rule would revise the requirements for when the claim ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products. In particular, because the claim indicates that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, we seek to limit the use of the claim to circumstances in which the food may help consumers achieve a healthy dietary pattern that conforms to current nutrition science and Federal dietary guidance.

B. Summary of the Major Provisions of the Proposed Rule

The proposed regulation would update the definition for the implied nutrient content claim ''healthy,'' which specifies the requirements for when the claim can be used on human food products. The claim ''healthy,'' when used in the nutritional context in food labeling, is an implied claim that the levels of the nutrients in the food are such that the food may help consumers maintain healthy dietary practices. Under the existing regulation, there are specific criteria for individual nutrients that must be met in the food for it to bear the claim, including limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts of nutrients whose consumption is encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. Since the time the claim was first defined in 1994, nutrition science and Federal dietary guidance have changed, making the current ''healthy'' definition outdated. Our current definition permits manufacturers to use the claim ''healthy'' on some foods that, based on the most up-to-date nutrition science and Federal dietary guidance, contain levels of nutrients that would not help consumers maintain healthy dietary practices. Further, a number of foods emphasized in current nutrition science and Federal dietary guidance as key elements of a healthy dietary pattern are not able to bear the ''healthy'' claim under the current regulation (*e.g.,* salmon due to fat levels). As a result, we believe that the definition needs to be updated so that the use of the claim will again accurately represent that the levels of the nutrients in the food may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance, as reflected in the *Dietary Guidelines for Americans, 2020–2025* (*Dietary Guidelines, 2020–2025*) (Ref. 1). The proposed framework for the updated definition of ''healthy'' uses a food group-based approach in addition to nutrients to limit (based on the understanding that each food group contributes an array of important nutrients to the diet). The proposed, updated ''healthy'' criteria would emphasize healthy dietary patterns by requiring that food products contain a certain amount of food from at least one of the food groups or subgroups recommended by the *Dietary Guidelines, 2020–2025* in order to be labeled ''healthy.'' The proposed regulation would also require a food product to be limited in certain nutrients, including saturated fat, sodium, and added sugars. The proposed rule would also add certain recordkeeping requirements for foods bearing the claim where compliance cannot be verified through information on the product label.

C. Legal Authority

We are issuing this proposed rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). We are also relying on our authority under sections 403(r), 403(a), 201(n) and 701(a) of the FD&C Act to propose certain records requirements.

D. Costs and Benefits

In the current marketplace, about 5 percent of all packaged foods are labeled as ''healthy.'' Because nutrition science has evolved over time, updating the definition of the implied nutrient content claim ''healthy'' to closely align with nutrition science underpinning the *Dietary Guidelines, 2020–2025* will better inform consumers who are selecting those products to choose a more healthful diet, which may result in lower incidence of diet-related chronic diseases, including cardiovascular disease and type 2 diabetes. Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity stemming from consumers that rely upon the ''healthy'' implied nutrient content claim selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Quantifiable costs to manufacturers associated with updating the ''healthy'' claim are reformulating, labeling, and recordkeeping. Discounted at 3 percent over 20 years, the mean present value of costs is estimated at $276 million, or $19 million annualized. Potential costs of rebranding certain foods are discussed qualitatively. Discounted at three percent over 20 years, the mean present value of benefits is estimated at $455 million, or $31 million annualized. Net benefits are estimated at $180 million, or $12 million annualized.

II. Introduction

In 1994, FDA issued a regulation defining ''healthy'' as an implied nutrient content claim pursuant to the Nutrition Labeling and Education Act (NLEA) of 1990. Implied nutrient

content claims were defined in our regulations, in part, as claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. At that time, nutrition science and Federal dietary guidance focused more on the individual nutrients contained in food. As a result, the criteria for ''healthy'' in the current regulation are solely based on individual nutrients. Nutrition science and Federal dietary guidance have evolved since the existing ''healthy'' regulation was issued in 1994. As the *Dietary Guidelines, 2020–2025* explains, current nutrition science focuses ''on consuming a healthy dietary pattern'' (Ref. 1). Although nearly all foods can be incorporated into a healthy dietary pattern to a greater or lesser extent, current nutrition science emphasizes nutrient-dense foods, such as fruits, vegetables, and whole grains, as key elements of a healthy dietary pattern. ''Nutrient dense'' foods and beverages are defined as foods and beverages that provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium (Ref. 1). These foods, which contain a variety of important nutrients, work synergistically as part of a dietary pattern to help improve health (Ref. 1). A number of these nutrient-dense foods are not able to bear the ''healthy'' claim under the current regulation (*e.g.,* salmon due to fat levels). Further, the current definition permits manufacturers to use the claim ''healthy'' on some foods that, based on the most up-to-date nutrition science and Federal dietary guidance, contain levels of nutrients that would not help consumers maintain healthy dietary practices (*e.g.,* certain ready-to-eat cereals that may be high in added sugars). Thus, we believe that the ''healthy'' claim definition needs to be updated in order to ensure that products bearing the claim are the products that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance.

FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity as nutrition-related chronic diseases are experienced disproportionately by certain racial and ethnic minority groups and those with lower socioeconomic status. We are committed to accomplishing this, in part, by empowering consumers with more informative and accessible labeling to choose healthier diets. By making nutrition information more available to consumers in a direct, accessible, and consistent manner, consumers will be able to make informed and healthful dietary choices. A key element in achieving these goals is updating our policies for nutrition-related labeling claims to reflect current nutrition science and Federal dietary guidance, which includes aligning with the updated Nutrition Facts Label and the *Dietary Guidelines, 2020–2025* (Ref. 1), and provide information in a way that is accessible to consumers. Claims like ''healthy'' provide information to consumers that allow them to quickly identify foods that can be the foundation of a healthy dietary pattern. Thus, the goal of this rulemaking is to update the definition of ''healthy'' as an implied nutrient content claim in the labeling of human food to help ensure that consumers have access to more complete, accurate, and up-to-date information about those foods.

To provide context regarding the scope of the problem Americans face from diet-related chronic disease, chronic diseases, such as heart disease, cancer, and stroke, are among the leading causes of death and disability in the United States, and half of all American adults have one or more preventable, diet-related chronic diseases, including cardiovascular disease and type 2 diabetes (Ref. 2). Each year, more than 630,000 Americans die from heart disease and close to 600,000 die from cancer (Ref. 3). An estimated 37 percent of Americans suffer from cardiovascular disease (CVD) (Ref. 4). As of 2017, 12.2 percent of the population 18 years and older had diabetes, 33.9 percent of adults had prediabetes (Ref. 5), and 38.4 percent of the population was predicted to be diagnosed with cancer during their lifetime (Ref. 6). As noted, many of these chronic diseases are experienced at higher rates by certain racial and ethnic minority groups and those with lower socioeconomic status. For example, in 2017–2018, more than 4 in 10 American adults had high blood pressure, and that number increases to about 6 in 10 for non-Hispanic Black adults (Ref. 27). Additionally, from 2017 to 2018, the prevalence of diagnosed diabetes was highest among American Indian and Alaska Native adults compared to other race-ethnicity groups (Ref. 28). While chronic diseases result from a mix of factors, unhealthy dietary patterns throughout the lifespan increase the risk of developing chronic diseases, along with genetic, biological, behavioral, socioeconomic, and environmental factors (Ref. 1).

Further, overweight and obesity, which are associated with poor eating and physical activity behaviors, are major contributors to chronic disease in the United States (Ref. 10). Obesity raises the risk for morbidity from chronic diseases such as type 2 diabetes, coronary heart disease, and some cancers, and is also associated with increased risk of all-cause and CVD mortality (Ref. 10). More than two-thirds of U.S. adults and nearly one-third of children and youth are overweight or obese (Ref. 11). These high rates of overweight and obesity and chronic disease have persisted for more than two decades and come not only with increased health risks, but also at high economic cost. According to the Government Accountability Office, in 2018, $383.6 billion was spent to treat CVD, cancer, and diabetes, making up 25 percent of the approximately $1.5 trillion in total health care spending on conditions among U.S. adults. In particular, government payers, including Medicare and Medicaid, account for more than 50 percent of spending for treatment of CVD, cancer, and diabetes (Ref. 29).

Improved nutrition represents an opportunity to help reduce the rates of these diet-related chronic diseases. As part of our nutrition work, we are taking actions to help consumers maintain healthy dietary patterns and make food choices that contribute to such patterns. A key source that has considered the current nutrition science and established recommendations on what healthy dietary patterns look like is the Dietary Guidelines document. The Dietary Guidelines are developed jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) and provide recommendations on healthy eating and the consumption of foods from various food groups, as well as the intake of specific macronutrients, such as saturated fats and added sugars, and micronutrients such as vitamins and minerals. The Dietary Guidelines are designed for policymakers and nutrition and health professionals to help all individuals and their families consume a healthy, nutritionally adequate diet (Ref. 1). The Dietary Guidelines are the foundation of Federal dietary guidance and are intended to inform policymakers when they implement Federal policies and programs related to food, nutrition, and health. The Dietary Guidelines, in addition to other consensus reports and scientific information, help FDA to shape regulations on nutrition-related claims

and other information that is permitted on a food label.

The *Dietary Guidelines, 2020–2025* explains that a healthy lifestyle—including following a healthy dietary pattern—can help people achieve and maintain good health and reduce the risk of chronic disease throughout all stages of the lifespan. The *Dietary Guidelines, 2020–2025* identifies vegetables, fruits, dairy, grains, protein foods, and oils as essential components of a healthy dietary pattern (Ref. 1). However, more than 80 percent of Americans have dietary patterns that are low in vegetables, fruits, and dairy (Ref. 1). Additionally, more than half of the population is meeting or exceeding the total grain and total protein foods recommendations but is not meeting the recommendations for the subgroups within each of these food groups (Ref. 1). In 2019, 42 percent of adolescents and 39 percent of adults said they ate fruit less than once a day, while 41 percent of adolescents and 21 percent of adults said they ate vegetables less than once a day (Ref. 13). At the same time, most Americans exceed the recommended intake limits for added sugars, saturated fats, and sodium, nutrients that should be limited in a healthy dietary pattern according to the *Dietary Guidelines, 2020–2025* (Ref. 1). Evidence shows that excess intake of these nutrients is associated with chronic disease risk; for example, diets lower in saturated fat may reduce the risk of CVD (Ref. 7), and high intakes of sodium are directly associated with elevated blood pressure, an important risk factor for CVD (Refs. 9, 10, and 17).

As consumers make their food purchases and daily food choices, food labeling provides them with valuable information about food groups, nutrients, and how a food from a particular food group fits into their daily diet. Claims on food packages such as ''healthy'' can provide quick signals to consumers about the healthfulness of a food or beverage, making it easier for busy consumers to select foods that can help build more healthful diets. To be accurate and effective, however, a claim of ''healthy'' must be based on current nutrition science and Federal dietary guidance to ensure that the foods bearing the claim in fact are useful to help consumers maintain healthy dietary practices.

We are thus proposing to update the implied nutrient content claim ''healthy,'' to make it consistent with current nutrition science and Federal dietary guidance. This update would modernize the criteria for the ''healthy'' claim to go beyond just individual nutrients to also incorporate the variety of nutrients present in a food, through the new food group requirements. This change would better reflect the overall nutrient content of the food, including nutrient density, to represent how nutrients work together and make up the food groups and subgroups that are part of a healthy dietary pattern. Aligning the concept of what it means to qualify for the ''healthy'' claim with current nutrition science and Federal dietary guidance, and its focus on nutrient density, will help ensure that the ''healthy'' claim is accurate and empowers consumers with information to make healthier decisions. Because we understand that there may be some reluctance by some food manufacturers to use the claim with the current regulatory definition, as it is not consistent with current nutrition science and Federal dietary guidance, we also expect that our proposed updated criteria for the ''healthy'' nutrient content claim may expand the availability of food labeled with the ''healthy'' claim for consumers in the marketplace due to manufacturers being more willing to use the updated claim.

III—Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
CVD	Cardiovascular Disease.
Dietary Guidelines	Dietary Guidelines for Americans.
DV	Daily Value.
DRV	Daily Reference Value.
c-eq	Cup Equivalent.
DRI	Daily Reference Intake.
DGAC	Dietary Guidelines Advisory Committee.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FGE	Food Group Equivalent.
HHS	U.S. Department of Health and Human Services.
G	Gram.
IOM	Institute of Medicine.
OMB	Office of Management and Budget.
National Academies	National Academies of Sciences, Engineering, and Medicine.
NFL Final Rule	Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule.
NLEA	Nutrition Labeling and Education Act.
oz-eq	Ounce Equivalent.
Mg	Milligram.
Oz	Ounce.
PRA	Paperwork Reduction Act.
RDI	Reference Daily Intake.
RACC	Reference Amount Customarily Consumed.
RFI	Request for Information.
PHO	Partially Hydrogenated Oil.
USDA	U.S. Department of Agriculture.
Dietary Guidelines, 2020–2025	*Dietary Guidelines for Americans, 2020–2025.*
2020 DGAC Report	Scientific Report of the 2020 Dietary Guidelines Advisory Committee.

IV. Background

A. Regulatory History

In the **Federal Register** of May 10, 1994, we published a final rule entitled ''Food Labeling: Nutrient Content Claims, Definition of Term: Healthy'' amending § 101.65(d) to define the term ''healthy'' as an implied nutrient content claim under section 403(r) of the FD&C Act (59 FR 24232). The definition in § 101.65(d) establishes parameters for use of the implied nutrient content claim ''healthy'' or related terms (such as ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') on the label or in the labeling of a food that is useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions. Under the existing regulation, these conditions include specific criteria for nutrients that must be met in the food for it to bear such claims. These criteria include limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts (10 percent of Daily Value (DV)) of nutrients whose consumption is encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. Under the regulation, foods must meet all limits and contain the minimum amount of at least one nutrient to encourage to bear the ''healthy'' claim. The required nutrient criteria vary for certain food groups (*e.g.,* there are different criteria for seafood, game meat, and raw fruits and vegetables) (§ 101.65(d)(2)). The current claim is also linked to use with an explicit or implicit claim or statement about a nutrient (*e.g.,* ''healthy, contains 3 grams of fat'').

B. Need To Update ''*Healthy*''

The existing definition in § 101.65(d) is linked to certain requirements in the Nutrition Facts label at 21 CFR 101.9 and serving size regulations at 21 CFR 101.12 that were in effect in 1994 when the final rule to define the nutrient content claim ''healthy'' was published. For example, the existing ''healthy'' regulation requires that a product provide a specified percentage of the RDI or Daily Reference Value (DRV) for nutrients that were of ''sufficient public health significance to warrant their inclusion on the nutrition label'' (59 FR 24232). Since that time, FDA has issued final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information. This includes the final rules ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742, ''NFL Final Rule'') and ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (81 FR 34000, ''Serving Size Final Rule''), which were published on May 27, 2016. These rules included changes to the nutrients that must be declared on the Nutrition Facts label. For example, the Nutrition Facts label must now include a declaration of the amount of added sugars in a serving of a product, based on our conclusion that evidence on dietary patterns and health outcomes supports a mandatory declaration of added sugars (81 FR 33742 at 33799). The updates also included changes to the DV of certain individual nutrients to reflect changes in recommended intake levels based on current nutrition science. The Nutrition Facts label declaration requirements and DVs for individual nutrients significantly inform the regulations for nutrient content claims such as ''healthy,'' including the updated criteria outlined in this proposed rule. The NFL Final Rule and the Serving Size Final Rule reflect the nutrition science in the 2015–2020 *Dietary Guidelines,* other consensus reports, national survey intake data, and research regarding consumer use and understanding of the label.

The Dietary Guidelines are published every five years to reflect current nutrition science. Although some of its specific recommendations have evolved as scientific knowledge has grown, many of its foundational recommendations have remained consistent over time (*e.g.,* recommending increased consumption of fruits, vegetables, and whole grains, and diets low in saturated fat and sodium). Advancements in nutrition science have provided a greater understanding of, and focus on, the importance of healthy dietary patterns, and how dietary components act synergistically to affect health. The *Dietary Guidelines, 2020–2025* has a particular focus on the importance of dietary patterns as a whole, with recommendations to help Americans make choices from across and within all food groups within calorie needs to add up to an overall healthy dietary pattern (Ref. 1). The *Dietary Guidelines, 2020–2025* also emphasizes ''shifts,'' or replacement of less healthy food choices with nutrient-dense foods, as a method for consumers to achieve a healthy dietary pattern. The body of scientific evidence discussed in the *Dietary Guidelines, 2020–2025,* and the recommendations based on that nutrition science, inform this proposed rule.

As stated above, a key element in helping to reduce the burden of nutrition-related chronic diseases and advance health equity is updating FDA's policies for nutrition-related labeling claims to ensure that they reflect current nutrition science and Federal dietary guidance, and provide information in ways that are useful and easier to understand for consumers. Because the implied nutrient content claim ''healthy,'' as codified at § 101.65(d)(2), is linked to the nutrition labeling regulations and dietary guidance that were in effect at the time of its issuance in 1994, we propose to update the criteria for ''healthy'' to ensure they are harmonized with current regulations, nutrition science, and Federal dietary guidance.

The framework underlying the existing ''healthy'' claim is, in some respects, inconsistent with current nutrition science and Federal dietary guidance. For example, the *Dietary Guidelines, 2020–2025,* which reflects current nutrition science, is centered on the importance of dietary patterns; their recommendations focus on the combination of nutrient-dense foods and beverages that people should consume to meet nutritional needs within calorie limits (Ref. 1), rather than focusing on individual nutrients. Nutrient density is important, among other reasons, because consumption of nutrient-dense foods provides beneficial nutrients, with little added sugars, saturated fat, or sodium. In contrast, the existing criteria for ''healthy'' only include requirements for individual nutrients. Under the solely individual nutrient-based framework, foods that are encouraged by the *Dietary Guidelines, 2020–2025* for inclusion in a healthy dietary pattern are sometimes not able to meet the nutrient criteria under § 101.65(d) for use of the claim ''healthy.'' For example, although consumption of certain oils, such as olive and canola oil, in place of sources of saturated fat, is supported by current nutrition science and emphasized by Federal dietary guidance (such as the *Dietary Guidelines, 2020–2025*) as part of a healthy dietary pattern, these oils are currently ineligible to bear the ''healthy'' claim, in part, because they do not contain 10 percent of the DV for vitamin A, vitamin C, protein, dietary fiber, calcium, or iron as specified by the existing rule. Thus, the existing ''healthy'' claim has become inconsistent with the longstanding

purpose of this type of implied claim to indicate that the nutrient levels in a food may help consumers maintain healthy dietary practices.

To the extent that current nutrition science and Federal dietary guidance (such as the *Dietary Guidelines, 2020–2025*) do still focus on individual nutrients (*e.g.,* recommending limits on saturated fat, sodium, and added sugars; identifying certain underconsumed nutrients), there have been some developments in scientific understanding related to intake of such nutrients. For example, Federal dietary guidance has shifted from recommending diets low in total fat (Ref. 12) to emphasizing increased intakes of monounsaturated and polyunsaturated fats and decreased intakes of saturated fat (Ref. 1). Additionally, current nutrition science, as reflected in the *Dietary Guidelines, 2020–2025,* recommends limiting consumption of foods higher in added sugars, which provide excess calories to the diet without contributing significant amounts of essential nutrients. In contrast, the existing ''healthy'' criteria include limits on total fat and do not include limits for added sugars, which makes the criteria inconsistent with current nutrition science and Federal dietary guidance.

Finally, as noted above, the existing definition for healthy includes a nutrient contribution criterion focused on nutrients that had sufficient public health significance to warrant their inclusion on the nutrition label and that had been highlighted by leading health authorities as being important to the public health (59 FR 24232 at 24243). At the time the existing ''healthy'' regulation was finalized in 1994, the nutrients included in the nutrient contribution requirement were vitamin A, vitamin C, protein, iron, calcium, and dietary fiber. Nutrient intakes have shifted over time, and vitamins A and C are no longer considered nutrients of public health significance because deficiency of these nutrients in the U.S. population is rare and not currently of substantial public health concern. In our recent updates to the Nutrition Facts label, we required declaration of vitamin D and potassium, but no longer required declaration of vitamins A and C (81 FR 33742 at 33744). These updates are consistent with the *Dietary Guidelines, 2020–2025,* which includes calcium, potassium, dietary fiber, and vitamin D as nutrients of public health concern, in addition to iron, for certain population groups (Ref. 1). Thus, in addition to a shift in focus from consumption of individual nutrients to healthy dietary patterns as the primary way to achieve nutritional adequacy, there have been some changes in Federal dietary guidance regarding individual nutrients since the original ''healthy'' rule was issued.

Noting the changes to the Nutrition Facts label, current nutrition science, and the *Dietary Guidelines, 2020–2025,* a variety of stakeholders, including from academia, industry, and consumers, have requested that we update the implied nutrient content claim ''healthy.'' Some stakeholders have provided specific recommendations on how they believe we should approach such an update. For example, in a citizen petition dated December 1, 2015 (Docket No. FDA–2015–P–4564) (''Kind Citizen Petition''), KIND LLC requested that we make certain changes to existing nutrition claim regulations, including a number of changes specifically related to the nutrient content claim ''healthy.''

C. Actions Taken To Update ''Healthy''

Because the framework for many of our nutrition labeling regulations is linked to elements in the Nutrition Facts label and serving size regulations, we have already taken several steps toward harmonizing the ''healthy'' nutrient content claim with our updated regulations and current nutrition science. In the **Federal Register** of September 28, 2016 (81 FR 66527), we published a notice of availability of a final guidance entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry.'' The guidance describes our intent to reevaluate the existing criteria for ''healthy'' in light of the changes to the Nutrition Facts label and serving size regulations, as well as the changes in nutrition science as reflected in the Dietary Guidelines. The guidance also advises manufacturers of our intention to exercise enforcement discretion with respect to some of the existing criteria for the nutrient content claim ''healthy'' until we amend § 101.65(d)(2). The guidance is available at: *https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf.*

Specifically, the guidance advises food manufacturers of our intent to exercise enforcement discretion with respect to the implied nutrient content claim ''healthy'' for foods that have a fat profile of predominantly monounsaturated and polyunsaturated fats, but do not meet the regulatory definition of ''low fat,'' and on foods that contain at least 10 percent of the DV per reference amount customarily consumed (RACC)[1] of potassium or vitamin D. This guidance reflects the changes in science and the Dietary Guidelines as described above related to intake of dietary fat and the changes in the nutrients of public health concern since the ''healthy'' definition was originally issued.

In September 2016, we also announced the establishment of a docket (Docket No. FDA–2016–D–2335) to receive information and comments (request for information or RFI) on the use of the term ''healthy'' in the labeling of human food products (81 FR 66562, September 28, 2016). In the RFI, we invited interested persons to comment on the Kind Citizen Petition; the use of the term ''healthy'' as a nutrient content claim in the labeling of human food products; and when, if ever, the use of the term ''healthy'' may be false or misleading. We also sought input on 12 specific questions and asked interested parties to provide supporting data, consumer research, and other information to support their comments and answers to our questions. Along with the RFI, we held a public meeting on March 9, 2017, entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products'' (Ref. 13). The purpose of the public meeting was to give interested persons an opportunity to discuss the use of the term ''healthy'' in the labeling of human food.

Overall, the comments to the docket (nearly 1,200) and at the public meeting supported updating the criteria for the ''healthy'' nutrient content claim to reflect current nutrition science and the Dietary Guidelines. Most health organizations, industry representatives, and consumers supported an enforceable, specific definition that would help guide consumers toward healthier options. There was broad support for limiting certain nutrients, especially added sugars, in foods labeled ''healthy,'' and in allowing whole, nutrient-dense foods and foods high in monounsaturated and polyunsaturated fats to meet the definition. Comments to the docket provided specific recommendations for nutrient criteria, whole food servings, and flexibility for different food categories. While there was some variation in the specific criteria proposed in comments, virtually all of the proposed frameworks included a combination of nutrient criteria and food group requirements.

Some comments from consumers, and a few comments from industry and

[1] Our regulations at § 101.12(b) establish RACCs for specified product categories that manufacturers can use to determine the required label serving size.

health organizations, expressed hesitation at the notion of a ''healthy'' nutrient content claim. Their primary concerns were that ''healthy'' could be too simplistic, could deter consumers from looking further into a product's nutritional content, could lead to excessive consumption of ''healthy'' products, or could mean different things to different consumers (*e.g.,* some consumers may not understand ''healthy'' in a nutritional context, but, rather, as referring to other aspects of the product, such as its production method (*e.g.,* organic)). FDA notes that the claim is not new and has been used on food product labels for decades, but we welcome additional comments on these issues in the context of this proposed rule.

We carefully considered comments received in response to the RFI and are addressing many aspects of the concerns noted within those comments in this proposed rule. We view the ''healthy'' claim as an opportunity to signal and provide information to consumers on which food products, because of their nutrient content, can be most helpful in maintaining healthy dietary practices, based on current nutrition science and Federal dietary guidance. The availability of a revised, updated ''healthy'' claim may also result in some members of the food industry developing and/or reformulating food products to better match current nutrition science recommendations and use the claim. Given the widespread support for updating ''healthy'' along with the need to align the claim with current nutrition science, we are proposing updated criteria for the claim.

D. Table of Past Publications Referenced in This Proposed Rule

Title	Publication date	Citation
Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms Final Rule.	January 6, 1993	58 FR 2302
Food Labeling: Nutrient Content Claims, Definition of Term: Healthy Final Rule	May 10, 1994	59 FR 24232
Food Labeling: Revision of the Nutrition and Supplement Facts Labels Final Rule	May 27, 2016	81 FR 33742
Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments Final Rule.	May 27, 2016	81 FR 34000
Notice of Availability for a Final Guidance ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry''.	September 28, 2016	81 FR 66527
Request for Information on the Use of the Term ''Healthy'' in the Labeling of Human Food Products.	September 28, 2016	81 FR 66562

V. Legal Authority

We are issuing this proposed rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the FD&C Act. These sections authorize FDA to adopt regulations that prohibit labeling that is: (1) false and misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from consuming the food or (2) uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

Congress passed the Nutrition Labeling and Education Act (NLEA) of 1990 (Pub. L. 101–535), with three basic objectives: (1) to make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary of HHS, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods (58 FR 2302, January 6, 1993). The NLEA created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (q)(2) to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) & (r)(2)(A) of the FD&C Act). Such claims are referred to as ''nutrient content claims.''

Nutrient content claims can either be claims that expressly characterize the level of a nutrient (express claims, such as ''low fat'') or claims that by implication characterize the level of any nutrient (implied claims, like the ''healthy'' claim). Nutrient content claims are typically based per RACC. This allows nutrient content claims on foods to be considered consistently across products and product sizes. In rulemaking to implement section 403(r)(1)(A) and 403(r)(2) of the FD&C Act shortly after the enactment of the NLEA, we determined that a claim that states that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is a claim that characterizes the levels of nutrients in a food (''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms,'' 58 FR 2302 at 2374–75, January 6, 1993). That rulemaking resulted in regulations defining ''implied nutrient content claims,'' in part, as claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. As the preamble explained, ''[t]he claims are essentially saying that the levels of nutrients in the food are such that the food will contribute to good health'' (58 FR 2302 at 2375).

FDA issued another implementing regulation in 1994, in which we defined ''healthy'' when the term is used as an implied nutrient content claim (59 FR 24232, May 10, 1994). We explained in the preamble to the 1994 final rule that the statute requires that FDA define terms by regulation before they are used as nutritional claims in food labeling; more specifically, under the terms of section 403(r)(1)(A) and 403(r)(2) of the FD&C Act, a nutrient content claim would misbrand a food unless it is made in accordance with a definition of the Secretary (and, by delegation, FDA) or with one of the other provisions in section 403(r)(2) of the FD&C Act (59 FR 24232 at 24234). The preamble explained that FDA had already determined that, when used in the nutritional labeling context, the term ''healthy'' is making an implied claim about the levels of the nutrients in the food; that is, that these levels are such that the food would be useful in achieving a total diet that conforms to current dietary recommendations (56 FR 60421 at 60423, November 27, 1991). Accordingly, FDA was establishing a

definition for ''healthy'' when it is used in a nutritional context.

In this rulemaking, we are proposing to update the definition of ''healthy'' when used as an implied nutrient content claim based on developments in current nutrition science and Federal dietary guidance, as we did with the rulemaking updating the Nutrition Facts label. Our proposed, updated criteria for ''healthy'' incorporate both food group and nutrient-to-limit requirements. These changes are intended to ensure that foods bearing the implied nutrient content claim ''healthy'' are foods that may help consumers maintain healthy dietary practices, based on current nutrition science and Federal dietary guidance. The fundamental purpose of this rulemaking furthers the congressional objectives underlying the NLEA of providing nutrition information to consumers to help in selecting foods that can lead to healthier diets and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

The proposed revised definition of ''healthy'' is consistent with the statutory language, particularly in light of the way current nutrition science and Federal dietary guidance, such as the Dietary Guidelines, have evolved and built upon previous editions. The Dietary Guidelines reflect the consensus scientific understanding that nutrients are not consumed in isolation and focus their recommendations on consuming a variety of nutrient-dense foods, across all food groups, as part of a healthy dietary pattern. The statutory language describes nutrient content claims as claims in the label or labeling of a food that ''expressly or by implication'' ''characterize the level of any nutrient in a food'' (section 403(r)(1)(A) of the FD&C Act). The claim ''healthy'' on its face is an implied claim because it suggests that the food, because of its nutrient content, may help consumers maintain healthy dietary practices. In the 1994 definition of the claim, levels for nine different individual nutrients were discussed: fat, saturated fat, cholesterol, vitamin A, vitamin C, calcium, iron, protein, and fiber (21 CFR 101.65(d)(2)(i)). As discussed elsewhere in this document, in recent years the Dietary Guidelines have shifted to recommending healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet (*Dietary Guidelines, 2020–2025*). Specifically, the *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through a variety of nutrient-dense foods. Additionally, the *Dietary Guidelines, 2020–2025* recommends increasing intakes of food groups to move intakes of underconsumed dietary components closer to recommendations.

Accordingly, the new proposed definition includes food groups that provide a number of different nutrients and is thus characterizing the overall nutrient content of the food, rather than focusing on one individual nutrient in isolation, as with an express nutrient content claim. Each food group that is included in the food group requirement for the proposed updated definition of the ''healthy'' claim represents the inclusion of multiple important nutrients. Therefore, the use of food groups better accounts for how all these nutrients contribute to, and may work synergistically to create, a healthy dietary pattern and improve health outcomes. By requiring products to contain a certain amount of a food group, the proposed rule will help ensure foods bearing the ''healthy'' claim contain a variety of important beneficial nutrients and, therefore, help Americans meet recommended nutrient intakes and maintain healthy dietary patterns. Consistent with Congress's objectives to provide appropriate nutritional information to consumers, and based on current nutrition science and Federal dietary guidance, the statutory phrase ''characterize the level of any nutrient in a food'' encompasses both limits on certain individual nutrients and food group criteria that more broadly incorporate a variety of nutrients from nutrient dense foods which may also have a synergistic effect.

In addition to section 403(r)(2) of the FD&C Act, we are issuing this proposed rule under section 701(a) of the FD&C Act, which states that we may issue regulations for the efficient enforcement of the FD&C Act and has been interpreted to apply in order to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980)).

We are also relying on our authority under sections 403(r), 403(a), 201(n) and 701(a) of the FD&C Act, to propose records requirements designed to ensure that the use of the ''healthy'' claim is accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where FDA has found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The recordkeeping we propose to require applies only to foods voluntarily bearing the ''healthy'' claim for which an adequate analytical method to determine food group equivalents is not available or the amount cannot be discerned from the label alone. The records would allow us to verify that the product meets the requirements to bear the claim and that use of the nutrient content claim ''healthy'' is truthful and not misleading. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act (see discussion in section VI.B.4 ''Records Requirements'' for more information).

The authority granted to FDA under sections 701(a), 403(r), 403(a)(1) and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without access to such records, FDA would not know whether the food meets the proposed requirements to bear the ''healthy'' claim consistent with section 403(r) of the FD&C Act, and whether the use of the claim is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether a food that is voluntarily bearing a ''healthy'' nutrient content claim is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be kept under proposed § 101.65(d)(4) (21 CFR 101.65(d)(4)). Failure to make and keep records and provide the records to FDA, as described in proposed § 101.65(d)(4), would result in the food bearing the ''healthy'' claim being misbranded under sections 403(r) and 403(a)(1) of the FD&C Act.

VI. Proposed Action

We propose to update the ''healthy'' nutrient content claim to align its criteria with our updates to the Nutrition Facts label and with current nutrition science and Federal dietary guidance, especially the *Dietary Guidelines, 2020–2025.* We also took several additional factors into

consideration while developing the proposed, updated criteria for ''healthy.'' We intend for the updated ''healthy'' criteria to help identify and encourage consumption of nutrient-dense foods to meet current nutrition science and Federal dietary guidance, especially the intake recommendations of the individual food groups as discussed in the *Dietary Guidelines, 2020–2025.* We also intend for the ''healthy'' criteria to be appropriately flexible to allow for industry innovation, thereby increasing the availability of foods in the marketplace that will help consumers meet dietary recommendations. Finally, we based the proposed criteria on well-established and longstanding foundations of dietary guidance, including food group recommendations and nutrients to limit.

A. Overview of Approach

The *Dietary Guidelines, 2020–2025* recommends following a healthy dietary pattern at every life stage with a focus on meeting food group needs with nutrient-dense foods and beverages, and staying within calorie limits. Specifically, the *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through a variety of nutrient dense foods. Additionally, the *Dietary Guidelines, 2020–2025* recommends increasing intakes of food groups to move intakes of underconsumed dietary components closer to recommendations. Consistent with current nutrition science and Federal dietary guidance, our proposed, updated criteria for ''healthy'' use an approach based on both food groups and nutrients to limit, rather than focusing solely on individual nutrients. The updated ''healthy'' criteria emphasize the food groups and subgroups identified in the *Dietary Guidelines, 2020–2025* as part of a healthy dietary pattern: vegetables, fruits, grains, dairy, and protein foods, as well as oils. Under the proposed, updated criteria, food products would need to contain a certain amount of food (a ''food group equivalent'') from at least one of these recommended food groups or subgroups (*e.g.,* ½ cup of fruit or ¾ cup of dairy) to be labeled ''healthy.'' The proposed incorporation of food group criteria is consistent with the current nutrition science articulated in the *Dietary Guidelines, 2020–2025* and its focus on dietary patterns as a whole and is appropriate for this implied nutrient content claim because claims that imply a food product contains a certain amount of a food group would characterize the level of a variety of nutrients important to help consumers maintain healthy dietary practices.

In addition to the food group criteria, we are proposing that foods must continue to adhere to certain criteria regarding nutrients to limit to be labeled ''healthy.'' Specifically, we propose maintaining sodium and saturated fat as nutrients to limit (which are already included in the current criteria), along with adding a limit on added sugars, consistent with the rationale for the new Nutrition Facts label requirement for added sugars declaration. These criteria are also consistent with the *Dietary Guidelines, 2020–2025* recommendations to limit intake of sodium, saturated fat, and added sugars, and, based on current nutrition science, would strengthen the public health benefits of foods bearing the ''healthy'' claim. The specific food group criteria and the nutrients to limit are discussed in further detail in sections VI.A.1 and VI.A.2 (''Food Groups'' and ''Nutrients to Limit'').

Because of the proposed food group approach, we propose that the ''healthy'' criteria no longer include minimum amounts of nutrients to encourage (*i.e.,* nutrients that are underconsumed and whose low intake in the general population or in individual subpopulations raise public health concern). The *Dietary Guidelines, 2020–2025* recommendations to consume various food groups and subgroups in certain quantities are intended to ensure overall nutritional adequacy and consumption in a manner to help consumers maintain healthy dietary practices. FDA is concerned that including criteria for nutrients to encourage could spur fortification to allow foods that are low in saturated fat, sodium, and added sugars to qualify for the ''healthy'' claim, despite these foods not contributing to a meaningful amount of a food group (*e.g.,* white bread fortified with calcium). FDA does not support indiscriminate fortification of foods but, rather, encourages the rational addition of nutrients to foods, as discussed further in our fortification policy guidance (Ref. 30). We request comment on whether nutrients to encourage should be included in addition to the food group criteria.

As described below, there are some foods that we propose to include in the updated criteria for ''healthy'' including raw, whole fruits and vegetables, and water, that under the proposed updated criteria, will not need to meet requirements for food group equivalents and nutrients to limit. These foods are included in categories of food that can automatically use the ''healthy'' claim because of their nutrient content and positive contribution to an overall healthy diet. This is not the case for these foods under the current rule; rather the individual fruit or vegetable must meet the criteria for the nutrients to limit (total fat, saturated fat, sodium, cholesterol) in order to bear the ''healthy'' claim. These exceptions will be discussed in further detail in section VI.B.3 (''Covered Products'').

1. Food Groups

Current nutrition science and Federal dietary guidance specifically emphasize the importance of following a healthy dietary pattern across the lifespan (Ref. 1). As described earlier, the *Dietary Guidelines, 2020–2025* notes that foods and beverages are not consumed in isolation, but rather in various combinations over time—a ''dietary pattern.'' Components of a dietary pattern may have interactive, synergistic, and potentially cumulative relationships, such that the dietary pattern may be more predictive of overall health status and disease risk than individual foods or nutrients (Ref. 1). The principal message of the *Dietary Guidelines, 2020–2025* is to follow a healthy dietary pattern that focuses on meeting food group needs with nutrient-dense foods and beverages and stays within calorie limits. The recommendations include an emphasis on meeting nutritional needs ''primarily from foods and beverages—specifically, nutrient-dense foods and beverages'' (Ref. 1), as opposed to dietary supplements. While FDA's definition includes dietary supplements as foods, they may not always be included in what the nutrition science literature refers to as ''foods.'' This recommendation also reflects the view that good nutrition does not come from intake of individual nutrients (as dietary supplements often provide) but rather from foods with their mix of various nutrients working together in combination. The *Dietary Guidelines,* 2020–2025 goes on to describe that ''[e]ating an appropriate mix of foods from the food groups and subgroups—within an appropriate calorie level—is important to promote health at each life stage. Each of the food groups and their subgroups provides an array of nutrients, and the amounts recommended reflect eating patterns that have been associated with positive health outcomes'' (Ref. 1, page 31). This focus on food groups is consistent with longstanding Federal nutrition education and messaging structured around food groups, such as those associated with MyPlate and the former MyPyramid Food Guidance System and Food Guide Pyramid (Ref. 14).

The *Dietary Guidelines, 2020–2025* further explains that a healthy dietary pattern includes:

- Vegetables of all types—dark green; red and orange; beans, peas, and lentils; starchy; and other vegetables;
- Fruits, especially whole fruit;
- Grains, at least half of which are whole grain;
- Dairy, including fat-free or low-fat milk, yogurt, and cheese, and/or lactose-free versions and fortified soy beverages and soy yogurt alternatives;
- Protein foods, including lean meats, poultry, and eggs; seafood; beans, peas, and lentils; and nuts, seeds, and soy products;
- Oils, including vegetable oils and oils in food, such as seafood and nuts.

In the *Dietary Guidelines, 2020–2025* and previous iterations, foods fit into groups based on how they are consumed, and their nutrient content, even if this is different from their botanical classification. For example, a bell pepper is considered a vegetable in the *Dietary Guidelines, 2020–2025* even though it is botanically a fruit. Additionally, foods from the same source may be categorized differently depending on how they are consumed. For example, soybean oil is classified as an oil, but tofu made from soybeans is classified as a protein food in the *Dietary Guidelines, 2020–2025.* In considering which foods contribute to meeting the individual food group requirements, we are adopting the categorizations used in the *Dietary Guidelines, 2020–2025* to determine the appropriate food group for the food. For example, in the previously mentioned bell pepper example, the presence of bell pepper ingredients would contribute to satisfying the vegetable food group requirements, rather than the requirements for fruit ingredients.

Evidence relied on in the *Dietary Guidelines, 2020–2025* shows that a healthy dietary pattern, as outlined above, is associated with beneficial outcomes for all-cause mortality, cardiovascular disease, overweight and obesity, type 2 diabetes, bone health, and certain types of cancer) (Ref. 1). Specifically, evidence shows that common characteristics of dietary patterns associated with positive health outcomes include relatively higher intake of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meats and poultry, seafood, nuts, and unsaturated vegetable oils, and relatively lower consumption of red and processed meats, sugar-sweetened foods and beverages, and refined grains (Ref. 1).

The existing criteria for ''healthy'' at § 101.65(d)(2) include minimum content thresholds for a limited number of nutrients for which consumption is encouraged. These nutrient criteria were originally included to identify foods that are particularly helpful to consumers in maintaining healthy dietary practices and achieving dietary recommendations. Instead of including a limited set of nutrients for which consumption is encouraged in the definition as surrogates for recommended food groups and subgroups, we propose to directly incorporate food groups as criteria in the definition of the claim ''healthy.'' We tentatively conclude that using food groups to encourage as the criteria for ''healthy,'' rather than a limited set of nutrients, would better identify foods with the nutrient content that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance. This approach is consistent with the *Dietary Guidelines, 2020–2025* focus on overall dietary patterns to ensure that a range of nutrients are consumed at appropriate levels, rather than on nutrients in isolation. We solicit comment on this tentative conclusion.

Our proposed criteria for updating ''healthy'' emphasize healthy dietary patterns by requiring that food products contain a certain amount of food from a recommended food group to bear the claim ''healthy.'' In this rule, the phrase ''food group'' refers to the groups of foods recommended in the *Dietary Guidelines, 2020–2025,* which include vegetables, fruits, dairy, grains, protein foods, as well as oils (Ref. 1). The *Dietary Guidelines, 2020–2025* does not categorize oils as a ''food group,'' but they emphasize that oils are one of the six core elements of a healthy dietary pattern, along with vegetables, fruits, grains, dairy, and protein foods, and recommend daily intake objectives for oils, similar to the food groups. Therefore, we will include oils as a food group for purposes of this rule. However, because of their specific role in healthy dietary patterns, the proposed criteria for oils differ from the criteria for other food groups, as discussed in further detail in section VI.B.3 (''Covered Products''). In this rule, the phrase ''food group equivalent'' refers to the amount of a food group that must be contained in a food product for it to bear the ''healthy'' claim. In this rule, the phrase ''food group equivalent'' refers to the amount of a food group that must be contained in a food product for it to bear the ''healthy'' claim.

We used the ''Healthy U.S.-Style Dietary Pattern,'' as described in table A3–2 in the *Dietary Guidelines, 2020–2025* (Ref. 1), using the 2000-calorie level pattern as the reference, to determine the food group equivalent amounts. We are basing our food group equivalent recommendations on amounts recommended at the 2,000 calorie level because 2,000 calories is often used for general nutrition advice and this reference amount is already used for other purposes in nutrition labeling. The 2000-calorie level pattern establishes specific daily food group and subgroup amounts in cup-equivalents (c-eq), ounce-equivalents (oz-eq), or grams (g), depending on the type of food. Cup- and ounce-equivalents identify the amounts of foods from each food group with similar nutritional content. For example, while the structural forms of whole wheat bread and brown rice are very different, the *Dietary Guidelines, 2020–2025* considers one medium (1 oz) slice of whole wheat bread to be nutritionally similar to one half cup of cooked brown rice, and both represent an oz-eq of whole grains. The 2000-calorie level dietary pattern establishes daily amounts for each food group as follows:

- 2½ c-eq of vegetables (comprising recommendations for vegetable subgroups);
- 2 c-eq of fruits;
- 6 oz-eq of grains, of which at least 3 oz-eq should be whole grains;
- 3 c-eq of dairy;
- 5½ oz-eq of protein foods (comprising recommendations for protein food subgroups, such as seafood); and
- 27 g of oils.

In past rulemakings, we have assumed that the typical American dietary pattern is three meals and one snack per day, *i.e.,* four eating occasions, not including beverage-only eating occasions (see final rules on general requirements for health claims and nutrient content claims in food labeling, 58 FR 2478 at 2495 and 58 FR 2302 at 2379 to 2380). In other words, we assume that individuals generally have four opportunities in a day to meet the recommended daily food group amounts in the Healthy U.S.-Style Dietary Pattern, and thereby satisfy their nutritional needs. Consistent with this assumption, and with our approach in past rulemakings, our proposed food group equivalents are based on four eating occasions per day. To determine the amount of a food group required for an individual food to bear the ''healthy'' claim, we divided the recommended daily food group amounts by four eating occasions. For example, because the recommended daily amount of fruit in the 2000-calorie level pattern is 2 c-eq, we determined that the food group equivalent for fruit would be ½ c-eq

(*i.e.,* 2 c-eq divided by four). This would mean that a ''fruit product'' would need to contain ½ c-eq of fruit per RACC (in addition to other requirements) to meet the proposed criteria for ''healthy.'' While this calculation provided a baseline amount for the food group equivalent requirements, we adjusted the baseline amount for certain food groups and subgroups, as warranted, based on considerations as described in section VI.B.3 (''Covered Products''). This calculation also informs the food group criteria for combination foods (foods that contain a meaningful amount of more than one food group) as will be discussed in section VI.B.3 (''Covered Products''). We seek comment on this proposed calculation—based on four eating occasions per day—for the food group equivalent requirement.

2. Nutrients to Limit

While our proposed updates to the ''healthy'' regulation reflect the importance of the overall nutrient content of foods that build dietary patterns rather than individual nutrients in isolation, we do propose keeping certain nutrients to limit as criteria for bearing the claim ''healthy.'' This is because current nutrition science and Federal dietary guidance continue to recommend limiting certain nutrients as a key component in emphasizing healthy overall dietary patterns. In the NFL Final Rule, we found that nutrition science supports limiting intake of saturated fat, sodium, and added sugars. Similarly, the *Dietary Guidelines, 2020–2025* includes recommendations to choose nutrient-dense foods across and within food groups while limiting foods and beverages higher in added sugars, saturated fat, and sodium (Ref. 1). Moreover, under the *Dietary Guidelines, 2020–2025,* ''nutrient dense'' food and beverages are defined as foods and beverages that provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium. Vegetables, fruits, whole grains, seafood, eggs, beans, peas, and lentils, unsalted nuts and seeds, fat-free and low-fat dairy products-, and lean meats and poultry—when prepared with no or little added sugars, saturated fat, and sodium—are identified as nutrient-dense foods (Ref. 1). Thus, in addition to the food group criteria for ''healthy,'' we are proposing updates to criteria for nutrients to limit for saturated fat, sodium, and are proposing to add criteria for added sugars. The proposed nutrients to limit criteria help ensure that foods bearing the ''healthy'' claim do not contain excess saturated fat, sodium, or added sugars, which can increase calories and/or the risk of chronic disease and therefore diminish the potential beneficial public health impact of the ''healthy'' claim.

In setting the criteria for nutrients to limit, we are proposing baseline values for each nutrient and have adjusted the values, as warranted. Different food groups and subgroups each contain foods that provide a variety of nutrients, including important nutrients that are underconsumed and some naturally contain higher amounts of nutrients that should be limited. For example, dairy foods provide vitamin D and calcium; however, they also may contain saturated fat. In contrast, fruits and vegetables contain minimal or no saturated fat. Using the same saturated fat criteria across all food groups could exclude foods that provide important nutrients and that are recommended by the Dietary Guidelines, such as low-fat milk and low-fat cheese. However, increasing the saturated fat limit across all food groups could encourage the unnecessary addition of saturated fat for foods in food groups such as vegetables, which are generally not sources of saturated fat. Therefore, based on current nutrition science and Federal dietary guidance, adjustments to the baseline amount for different food groups allow a variety of foods across recommended food groups to meet the proposed, updated definition without encouraging unnecessary addition of saturated fat, sodium, and added sugars. The adjustments made to the baseline amount for different food groups and subgroups are further described in section VI.B.3.b (''Individual foods'').

The baseline values are percentages of the DV for each nutrient to help ensure flexibility and longevity of the ''healthy'' criteria if the DVs shift in the future. DVs are reference amounts of nutrients to consume or not to exceed each day. Historically, the DVs established in regulation by FDA have been based on the nutritional needs of adults and children 4 years of age and older. However, the recent revisions to the regulations for the Nutrition Facts label have established DVs specific to infants up to 12 months of age and to children 1 to 3 years of age (§ 101.9(c)(9)). As discussed earlier, we are proposing that use of the nutrient content claim ''healthy'' remains limited to adults and children 2 years of age and older. Therefore, the claim ''healthy'' could appear on foods directed to children 2 to 3 years of age and on foods directed to adults and children 4 years of age and older. When determining eligibility for use of the claim ''healthy,'' specifically whether a food meets the ''percent DV'' criteria for saturated fat, sodium, and added sugars, the ''percent DV'' criteria will be based on the set of DVs appropriate for that food. For the majority of foods, the DVs established for adults and children 4 years of age and older will be the basis of the nutrient criteria for the claim that are discussed in the following sections. However, for the subset of foods specifically directed to children 2 to 3 years of age (*e.g.,* fruit pouches, toddler snack puffs), the basis of the ''percent DV'' nutrient criteria are the specific set of DVs established for that age range in § 101.9(c)(9).

a. Saturated Fat

The current ''healthy'' nutrient content claim regulation includes limits on saturated fat for all food categories (§ 101.65(d)(2)(i)(A)–(F)). Dietary recommendations have long recognized the well-established relationship between consumption of saturated fat and its effect on blood cholesterol levels (Refs. 16 and 17). Evidence shows that replacement of saturated fats with unsaturated fats, especially polyunsaturated fats, reduces blood total cholesterol and low-density lipoprotein cholesterol (LDL-cholesterol) concentrations and, therefore, the risk of CVD (Ref. 16). Evidence shows that replacing saturated fats with polyunsaturated fats is associated with a reduced risk of CVD mortality and/or coronary heart disease (CHD) (Ref. 16). Saturated fat is required to be declared on food labels by section 403(q)(1)(D) of the FD&C Act, and we reaffirmed in the NFL Final Rule that saturated fat declaration is necessary to assist consumers in maintaining healthy dietary practices (81 FR 33742 at 33786).

The DVs for nutrients are established either as RDIs or as DRVs. The DRV for saturated fat is 20 grams (for children 1 to 3 years old, the DRV is 10 grams), which is approximately 10 percent of calories based on a 2,000-calorie reference intake level (§ 101.9(c)(9)). In the preamble to the proposed NFL rule (79 FR 11879 at 11895, March 3, 2014, Docket No. FDA–2012–N–1210), we discussed how consensus reports (*e.g.,* Institute of Medicine (IOM) Dietary Reference Intakes (DRI) and 2002 report from the National Cholesterol Education Program of the National Institutes of Health's National Heart, Lung, and Blood Institute) continue to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. We reaffirmed in the NFL Final Rule that the 20-gram DRV is consistent with scientific evidence (81 FR 33742 at 33786). Additionally, the Dietary Guidelines have consistently

recommended limiting calories from saturated fats. The *Dietary Guidelines, 2020–2025* states that intake of saturated fat should be limited to less than 10 percent of calories per day by replacing them with unsaturated fats, particularly polyunsaturated fats. Accordingly, we propose limiting saturated fat in foods bearing the implied nutrient content claim ''healthy,'' to ensure that such foods do not contribute to a dietary pattern that contains excess saturated fat. Many of the comments on the RFI supported including a limit on saturated fat in foods bearing the ''healthy'' claim.

For saturated fat, we are proposing a baseline limit of 5 percent of the DV per RACC (≤1 g for adults and children 4 years of age and older). This level is consistent with the low saturated fat nutrient content claim (21 CFR 101.62(c)(2)), and with the saturated fat criteria for most of the individual foods in the current definition for ''healthy.'' We are also proposing to adjust the baseline limit for saturated fat, as warranted, based on specific nutrient considerations associated with the different food groups and subgroups and the Dietary Guideline consumption recommendations for different food groups. As discussed in section V.B.3.b (''Individual foods''), we are proposing the baseline limit for saturated fat (5 percent of the DV per RACC) for fruit products; vegetable products; grain products; bean, pea, and soy products; and nut and seed products (excluding saturated fat derived from nuts and seeds, as discussed in section VI.B.3.b (''Individual foods''). We are proposing the following adjustments to the baseline limit for saturated fat, as described further in the discussion of individual foods below, for certain categories of foods that are core elements of healthful dietary patterns associated with reducing chronic disease risk (*e.g.,* low-fat dairy products): 10 percent of the DV for dairy products; 10 percent of the DV for game meats, seafood, and eggs; and 20 percent of total fat for oils and oil-based spreads and dressings.

We are also considering alternatives to the proposed limits on saturated fat. We are considering an approach using a ratio of saturated fat to total fat, such as a ratio based on current DVs for saturated fat and total fat, which are based on 10 percent and 35 percent of daily calorie intake, respectively. The intent of this approach would be to apply a single ratio across all food groups, thereby reducing the variation in the currently proposed limits, while still allowing some flexibility for foods that provide monounsaturated and polyunsaturated fats. We seek comment on the use of a limit for saturated fat based on the ratio of saturated fat to total fat, including any data supporting this approach.

b. Sodium

The current ''healthy'' nutrient content regulation includes limits on sodium content for all food categories (§ 101.65(d)(2)(ii)). Dietary recommendations have long emphasized reductions in sodium intake because average population-level intake continually exceeds recommended levels. As we stated in the NFL Final Rule, evidence continues to support the association between increased sodium consumption and blood pressure (81 FR 33742 at 33875). For example, the National Academy of Medicine (formerly IOM), of the National Academies of Sciences, Engineering, and Medicine (National Academies), 2005 DRI Electrolytes Report noted a direct relationship between sodium intake and increased blood pressure (Ref. 9) and the 2013 National Academies report entitled ''Sodium Intake in Populations: Assessment of the Evidence'' (Ref. 8) concluded that a strong body of evidence has been documented in adults that blood pressure decreases as sodium intake decreases. The Scientific Report of the 2020 Dietary Guidelines Advisory Committee Report (2020 DGAC Report) states that sodium intake is directly related to blood pressure across the lifespan and that elevated blood pressure contributes to the risk of CVD and stroke, which are both leading causes of morbidity and mortality in the United States (Ref. 15).

Reducing sodium intake has also been a consistent recommendation in the Dietary Guidelines; the *Dietary Guidelines, 2020–2025* carries forward the National Academies' recommendation to limit sodium to less than 2,300 milligrams (mg) per day—and even less for children younger than age 14 (Refs. 1 and 17). According to the *Dietary Guidelines, 2020–2025,* healthy dietary patterns limit sodium to the Chronic Disease Risk Reduction (CDRR) levels defined by the National Academies—1,200 mg/day for ages 1 through 3; 1,500 mg/day for ages 4 through 8; 1,800 mg/day for ages 9 through 13; and 2,300 mg/day for all other age groups. However, average intakes of sodium are high across the U.S. population compared to the CDRR levels. Average intakes for those ages 1 and older is 3,393 mg/day, with a range of about 2,000 to 5,000 mg/day (Ref. 1). In 2019, the National Academies set the CDRR levels for sodium based on evidence of the beneficial effect of reducing sodium intake on blood pressure and risk of CVD and hypertension (Ref. 17). This most recent evaluation of the evidence reaffirms the 2,300 mg/day recommended daily limit for those 14 years and older. To reduce sodium intake to the recommended limits, the *Dietary Guidelines, 2020–2025* recommends implementing multiple strategies, including making food choices in all food groups with less sodium (Ref. 1). We propose to include a limit on the amount of sodium in foods bearing the nutrient content claim ''healthy'' to help individuals identify foods that are consistent with dietary recommendations for sodium. Many comments on the RFI supported a sodium limit on foods bearing the claim ''healthy.''

The DRV for sodium is 2,300 mg (for children 1 to 3 years old, the DRV is 1,500 mg). We are proposing a baseline sodium limit of ≤10 percent of the DV (currently, 230 mg for adults and children 4 years of age and older) per RACC for individual foods. This proposed, updated sodium limit is lower than the limit in the existing criteria for ''healthy'' (480 mg, or about 20 percent of current DV) (§ 101.65(d)(2)(ii)). We expect that it is feasible to lower the sodium level requirement for ''healthy'' due to reductions in sodium in certain foods and food categories in response to consumer support for policies to limit sodium content in manufactured foods (Refs. 18 and 19) and to technological progress since the existing definition of ''healthy'' was issued in 1994. Additionally, in October 2021, FDA published short-term (2.5 year) voluntary sodium reduction targets for the food industry (Ref. 31). These targets are anticipated to support gradual sodium reduction in the food supply and increase available options that are lower in sodium. When selecting the proposed, updated limit for the ''healthy'' claim, we considered the many functions of sodium in food, including taste, texture, microbial safety, and stability. For example, while a baseline limit for sodium of ≤5 percent of the DV would be consistent with the proposed saturated fat and added sugar baseline limits and the low sodium nutrient content claim, we are concerned that a limit of ≤5 percent of the DV for sodium is not practical at this time. We are proposing to adjust the baseline values for sodium as warranted, based on specific considerations of the different food groups and subgroups, as described below. We seek comment on this approach.

c. Added Sugars

In the NFL Final Rule, we required the declaration of the amount of added sugars in a serving of a product after we concluded that evidence on dietary patterns and health outcomes supports a mandatory declaration of added sugars (81 FR 33742 at 33799). We determined that declaration of the amount and percent DV of added sugars in a serving of a product is necessary to assist consumers to maintain healthy dietary practices and determine how a serving of a product fits into the context of their total daily diet (81 FR 33742 at 33804). This conclusion was based on scientific evidence showing that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD (Ref. 7). This is consistent with a key recommendation of the *Dietary Guidelines, 2020–2025* to limit foods and beverages higher in added sugars (Ref. 1). To achieve this recommendation, the *Dietary Guidelines, 2020–2025* recommends that individuals 2 years of age and older consume less than 10 percent of calories per day from added sugars.

Current consumption data indicate that most Americans are consuming more than 10 percent of calories from added sugars (Ref. 16). According to the 2020 DGAC Report, current intake of added sugars remains high at 267 calories, or 12.7 percent of total calories per day among the total population ages 1 year old and older (Ref. 16). Evidence shows that consumption of excess calories from added sugars can lead to a less nutrient-dense diet. When sugars are added to foods and beverages, the sugars add calories without contributing essential nutrients. Foods with added sugars displace other nutrient-dense foods in the diet, and as the amount of added sugars increase in the diet, it becomes more difficult to also eat foods with sufficient dietary fiber and essential vitamins and minerals and stay within calorie limits. Thus, a diet low in added sugars helps individuals achieve a healthy dietary pattern through nutrient-dense choices within calorie limits (Ref. 1). Many of the comments on the RFI and public meeting support limiting the amount of added sugars permitted in foods bearing the claim ''healthy.''

Consistent with our rationale in the NFL Final Rule and with the *Dietary Guidelines, 2020–2025,* we find that it is critical that foods bearing the implied nutrient content claim ''healthy'' do not contribute to a dietary pattern that contains added sugars over the recommended levels. We therefore propose including a limit on the amount of added sugars in foods bearing the nutrient content claim ''healthy'' to help consumers choose foods that will contribute to a healthy dietary pattern that is lower in added sugars, consistent with current nutrition science and Federal dietary guidance. The DRV for added sugars is 50 g (for children 1 to 3 years old, the DRV is 13 g). For individual foods, we are proposing a baseline value for added sugars of ≤5 percent of the DV per RACC (≤2½ g for adults and children 4 years of age and older). While there is no low added sugars nutrient content claim, the proposed ≤5 percent DV level is consistent with our approach of using a low in saturated fat claim, which the *Dietary Guidelines, 2020–2025* also recommends limiting to less than 10 percent of calories per day starting at age 2. We are also proposing to adjust the baseline values for added sugars as warranted, based on specific considerations of the different food groups and subgroups, as described in the discussion of individual food groups below. We seek comment on this approach.

We note that high-intensity (low- and no-calorie) sweeteners are not considered added sugars by FDA. Additionally, the *Dietary Guidelines, 2020–2025* does not consider high-intensity sweeteners to be added sugars and do not make any recommendations for those 2 years of age and older on the intake of high-intensity sweeteners. Therefore, high-intensity sweeteners are not a factor in this proposed rule. The *Dietary Guidelines, 2020–2025* did note that ''replacing added sugars with low- and no-calorie sweeteners may reduce calorie intake in the short-term and aid in weight management, yet questions remain about their effectiveness as a long-term weight management strategy.'' FDA reviews high-intensity sweeteners for use in foods based on available scientific evidence. There is reasonable certainty of no harm under the intended conditions of use of high-intensity sweeteners because the estimated daily intake is not expected to exceed the acceptable daily intake for each sweetener.

d. Nutrients Not Included

(1) Total Fat

In contrast to the existing criteria at § 101.65(d), we propose removing the limit for total fat in the updated criteria for ''healthy.'' Federal dietary guidance, based on current nutrition science, has shifted away from recommending diets low in total fat—which includes saturated fat, *trans* fat, and unsaturated fat—to focus instead on the types of fat in the diet due to their different effects on health outcomes. The *Dietary Guidelines, 2020–2025,* for example, includes no key recommendation for intake of total fat, and emphasize replacing intake of saturated fats with unsaturated fats, particularly polyunsaturated fats (Ref. 1). The shift away from emphasizing total fat is also reflected in the NFL Final Rule (81 FR 33742). For example, the declaration of ''Calories from fat'' is no longer required on the Nutrition Facts label because current nutrition science supports a view that the type of fat is more relevant than overall total fat intake in risk of chronic diseases. Reflecting this shift in science, our guidance for industry on the use of the term ''healthy,'' published in 2016, advises food manufacturers of our intent to exercise enforcement discretion for products labeled ''healthy'' that are not low in total fat, but have a fat profile makeup of predominantly monounsaturated and polyunsaturated fat (Ref. 19). Therefore, while we propose maintaining a limit on saturated fat, we are not proposing to include total fat as part of the criteria for the ''healthy'' nutrient content claim.

(2) Trans Fat

In 2015, we released a final determination that partially hydrogenated oils (PHOs) which are the primary dietary source of industrially produced *trans* fat, are no longer generally recognized as safe for use in food (80 FR 34650, June 17, 2015) to eliminate the majority of uses of PHOs. The compliance date for this determination was June 18, 2018, for most foods, with extended compliance dates in 2020 and 2021 for certain uses of PHOs (83 FR 23358, May 21, 2018). As a result of this determination, what was previously the primary dietary source of *trans* fat has been largely removed from the food supply.

We recognize that there are other sources of *trans* fat in the food supply, including refined edible oils and naturally occurring sources in products from ruminant animals (*e.g.,* meat and dairy). The *Dietary Guidelines, 2020–2025* does not make any recommendations regarding intake of *trans* fat but notes that the National Academies recommends that *trans* fat consumption be as low as possible without compromising the nutritional adequacy of the diet. However, because foods that contain declarable levels of *trans* fat from sources other than PHOs typically contain saturated fat as well, we expect that the proposed saturated fat limits will disqualify most foods containing declarable levels of naturally

occurring *trans* fat from meeting the ''healthy'' criteria (Ref. 20). Therefore, we are not proposing to include a limit for *trans* fat in the updated ''healthy'' criteria because we do not think such a limit is necessary due to the limits we are proposing for saturated fat in this rule and due to our other regulatory actions to remove PHOs from the marketplace. We seek comment on our proposed approach to *trans* fat, including any data demonstrating that the saturated fat limit will not adequately disqualify foods containing *trans* fat from meeting the proposed ''healthy'' definition.

(3) Dietary Cholesterol

The *Dietary Guidelines, 2020–2025* does not make any recommendations regarding intake of dietary cholesterol but discuss dietary cholesterol in conjunction with *trans* fat and note that the National Academies recommends that dietary cholesterol consumption be as low as possible without compromising the nutritional adequacy of the diet. The *Dietary Guidelines, 2020–2025* also notes that the USDA Dietary Patterns are limited in dietary cholesterol (Ref. 1). Additionally, the 2020 DGAC Report states that ''[b]ecause dietary cholesterol is found only in animal-source foods that are typically also sources of saturated fat, the independent effects on blood lipids and CVD are difficult to assess. Although, we recognize the importance of limiting dietary cholesterol, we tentatively conclude that it is unnecessary to include a limit for dietary cholesterol for the ''healthy'' claim because, as with *trans* fat, dietary cholesterol is already sufficiently limited by the proposed limits for saturated fat.

Dietary cholesterol and saturated fats are found in similar foods, *i.e.,* foods that are higher in dietary cholesterol, such as fatty meats and full-fat cheese, which are generally also higher in saturated fats (Ref. 16). As a result, a dietary pattern low in saturated fat is typically also low in dietary cholesterol. We therefore expect that the proposed saturated fat value of 5 percent DV per RACC (or the adjusted baseline limit for certain foods) will disqualify most foods that contain more than 60 mg of dietary cholesterol, the current limit under § 101.65, from meeting the proposed ''healthy'' criteria.

There are a few exceptions, including foods such as eggs and some shellfish, that contain ≤5 percent DV of saturated fat per RACC and are not low in dietary cholesterol (Ref. 20). However, eggs and seafood (which includes fish and shellfish) are specifically highlighted in the *Dietary Guidelines, 2020–2025* as being nutrient-dense foods, supplying nutrients such as choline, vitamin D, and essential fatty acids (Refs. 1 and 17). The *Dietary Guidelines, 2020–2025* also found that almost 90 percent of Americans do not meet the recommendations for consumption of seafood, and specifically recommend shifts within the protein foods group to increase seafood intake.

Because eggs and seafood are nutrient-dense foods, provide important nutrients, and are specifically recommended by the *Dietary Guidelines, 2020–2025* for inclusion in a healthy dietary pattern, we consider that it is appropriate for these foods to meet the updated ''healthy'' criteria. For these reasons, we are not proposing to include a limit on dietary cholesterol as part of the updated criteria for ''healthy.'' We seek comments on our proposed approach to dietary cholesterol, including any data showing that the proposed saturated fat limit does not adequately limit dietary cholesterol, or any data indicating that foods containing lower saturated fat levels and higher cholesterol levels (*i.e.,* seafood and eggs) should not bear the ''healthy'' nutrient content claim.

3. Infants and Children Under Two Years of Age

In developing updates to the criteria for ''healthy,'' we have also considered whether the proposed definition should be extended to cover foods targeted to those age groups. Defined nutrient content claims currently apply to foods intended for adults and children 2 years of age and older. With the exception of claims on the percent of the Reference Daily Intake (RDI) for vitamins and minerals, nutrient content claims currently cannot be made on foods intended specifically for use by infants and children less than 2 years of age (*e.g.,* jarred baby foods, fruit pouches, toddler snack puffs) unless the claim is explicitly provided for in the regulations for each individual claim (21 CFR 101.13(b)(3)). Thus, as with most other nutrient content claims, the current definition for the nutrient content claim ''healthy'' does not include provisions for foods intended specifically for use by infants and children less than 2 years of age.

Our tentative conclusion is to continue to limit the use of the claim to foods directed to adults and children 2 years of age and older. As described in section IV.C. (''Need to Update 'Healthy' ''), we relied primarily on the science articulated in the *Dietary Guidelines, 2020–2025* in developing the specific criteria on which to base the definition of ''healthy.'' Historically, the Dietary Guidelines have been directed to adults and children 2 years of age and older. The *Dietary Guidelines, 2020–2025* highlights the importance of encouraging healthy dietary patterns at every life stage, and have included new recommendations for healthy dietary patterns for infants and children younger than 2 years of age in this lifespan approach. Infants and children younger than 2 years of age have specific nutritional needs that apply to their particular life stages and their dietary recommendations are different from the recommendations for other age groups. In our last update to the Nutrition Facts label (81 FR 33742), we established Daily Values (DVs) specifically for infants 7 through 12 months and children 1 through 3 years of age. The science underlying the recommended intake levels of individual nutrients demonstrates the specific nutritional needs of infants and children in this life stage. Evaluating the specific nutritional needs of this population can help us in determining whether it is appropriate to extend use of the claim ''healthy'' to foods directed at infants and children younger than 2 years of age. We intend to consider the scientific information discussed in the *Dietary Guidelines, 2020–2025,* as well as information from other sources, as we evaluate whether specific criteria can be developed for foods targeted to infants and children in those age groups for use in the definition of ''healthy.'' Because we are continuing to evaluate the information on the nutritional needs of this life stage, at this time, we are not proposing that the updated definition of ''healthy'' apply to foods targeted to infants and children under 2 years of age.

B. Description of the Proposed Regulation

1. Terms Subject to Definition

''Healthy'' is a broad term that can have connotations beyond the nutritional properties of a food. This proposed rule would define ''healthy'' as a nutrient content claim only when it is used in a nutritional context; in other words, the proposed criteria would only apply when ''healthy'' is used on a label or in labeling and other information, such as other claims, images, or vignettes, about the nutrition content of the food is also present somewhere on the labeling. For example, if the word ''healthy'' is used above a picture of vegetables or alongside another nutrient claim such as ''0g of fat,'' that would clearly place it in the nutritional context. If, however,

the word ''healthy'' was used on a label to say ''our manufacturing processes support a healthy planet'' with an adjacent picture of the earth, that would not be in the nutritional context. Under proposed § 101.65(d)(1), this regulation would cover labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices because of its nutrient content, where there is also implied or explicit information about the nutrition content of the food (other than required disclosures, such as the Nutrition Facts Label) elsewhere on the label or in labeling.

We determined in the 1994 rule that the term ''healthy'' constitutes an implied nutrient content claim only when it appears on the label or labeling of a food in a nutritional context (59 FR 24232 at 24234 to 24235). We first determined that the term ''healthy'' does not *inherently* imply the absence or presence of a nutrient in a particular amount, or that the nutrient content of the food would be helpful to consumers in structuring a diet that conforms to the Dietary Guidelines. Rather, such inferences are likely to be drawn only if the term ''healthy'' is accompanied by additional language or graphic material or is otherwise presented in a context that explicitly or implicitly suggests that the food has a particular nutrient content. Based on this reasoning, we concluded that the nutritional context is a critical factor as to whether ''healthy'' is used as an implied nutrient content claim.

We reaffirm our position in the 1994 rule that ''healthy'' is only an implied nutrient content claim when used in a nutritional context, as described above. However, we propose some minor revisions to § 101.65(d)(1)(ii) defining implied nutrient content claims. Under the existing regulation, labeling claims are implied nutrient content claims when they are made in connection with an explicit or implicit claim or statement about a nutrient (such as ''healthy, contains 3 grams of fat'').

While we want to ensure that the regulation only reaches claims that are made in a nutritional context, based on our years of experience with the current claim, we think the existing language may be too narrow and not reach all information about nutritional context. Further, because this proposed rule would expand the criteria for ''healthy'' to incorporate food group requirements in addition to individual nutrients to limit, we want to ensure that the regulation encompasses the full range of nutrition information covered by the rule. Based on these considerations, we propose revising the existing text to broaden the description of what a nutritional context entails. We seek comment on the definition of nutritional context provided here.

Specifically, we propose revising § 101.65(d)(1)(i) and (ii) to appear as § 101.65(d)(1). Proposed § 101.65(d)(1), as revised, would no longer require that an implied nutrient content claim be used ''in connection with an explicit or implicit claim or statement about a nutrient.'' Instead, we propose in § 101.65(d)(1) that ''healthy'' constitutes a nutrient content claim where the term ''healthy'' is used to characterize the food itself and ''where *there is also* implied or explicit information about the nutrition content of the food.'' This clarifies that the information on the label that places use of the claim ''healthy'' into a nutritional context would not necessarily be immediately adjacent to the implied nutrient content claim, as in the ''healthy, contains 3 grams of fat'' example. Instead, we propose to make clear that any information on the label or labeling that puts the term ''healthy'' into a nutritional context would make ''healthy'' an implied nutrient content claim when it is used to characterize the food. For example, where ''healthy'' appears on the front of a cereal product that is described elsewhere on the label or labeling as high in dietary fiber (*e.g.,* on the back of the package, or on a website), the ''healthy'' claim would constitute a nutrient content claim under § 101.65(d). There may also be instances where the use of a graphic on the label of a food bearing ''healthy'' would place the term in a nutritional context; for example, if the label on a can of beans labeled ''healthy'' also used the MyPlate symbol (which graphically puts the food groups together in the context of an overall dietary pattern, as a translation of the *Dietary Guidelines*) or other front of pack labeling (such as the ''Facts Up Front'' labeling program) to imply that the product meets nutritional needs (Ref. 32). In addition, some brands include ''healthy'' or related words in their brand name, which could be considered an implied nutrient content claim if any other information on the label or labeling puts the term ''healthy'' into a nutritional context—for example, if a food product included ''healthy'' within the brand name also used the ''low sodium'' nutrient content claim. FDA considers food labels and labeling as a whole and will consider the context of statements made in labels and labeling to determine whether a product bears a ''healthy'' implied nutrient content claim.

We also propose revising the codified text in § 101.65(d)(1) to no longer require that the accompanying material be a ''claim or statement about a *nutrient*.'' It would instead require that it be ''information about the *nutrition content of the food*.'' This text is still intended to ensure that the regulation only applies where a ''healthy'' claim is used in a nutritional context. However, it would not limit the accompanying material on the labeling to phrases declaring presence/level of a specific nutrient (as in the ''healthy, contains 3 grams of fat'' example), but include any material stating or implying that the nutrient content of the food would be helpful to consumers in structuring a diet that is supported by current dietary recommendations. For example, if a cereal package bore the claim ''healthy'' as a descriptor of the cereal, and its labeling elsewhere stated, ''Provides all of your child's essential vitamins and minerals,'' this would constitute an implied nutrient content claim, because in that context, the ''healthy'' claim suggests that the nutrient content of the food would be helpful in structuring a diet that conforms to current dietary recommendations. Information about the nutrition content of the food need not make explicit references to nutrients but can refer to nutrients by implication. For example, if the label on a food product characterizes food using the term ''healthy'' and elsewhere stated that the product is ''made with whole grain ingredients,'' or ''made with real fruits and vegetables,'' or ''contains a variety of nuts,'' this would put ''healthy'' in a nutritional context because the labeling implies that the food should contain nutrients commonly associated with and contributed by those food components.

We therefore propose that the updated § 101.65(d)(1) state that it covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food. Additionally, because the language in § 101.13(b)(2)(ii) parallels the definition of ''healthy'' in § 101.65, we are also proposing to update the language in § 101.13(b)(2)(ii) to provide that an implied nutrient content claim suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food (*e.g.,* healthy).

Under the proposed regulation, ''healthy,'' when used outside of a nutritional context, would not be an implied nutrient content claim. However, even outside of the nutritional context, we have the authority under the misbranding provisions at section 403(a) of the FD&C Act, to ensure that ''healthy'' is not used in a misleading manner. The proposed regulation also does not address use of the term ''healthy'' when used as part of an implied health claim (*e.g.,* ''heart healthy'') instead of a nutrient content claim. See 21 CFR 101.14 for information on the use of express and implied health claims.

2. Food Group Equivalents

As explained in section VI.A (''Overview of Approach''), a food group equivalent is the amount of a food from a particular food group that must be contained in a food product for it to bear the ''healthy'' claim. Proposed § 101.65(d)(2) would define a ''food group equivalent'' as equal to the following:

- A food group equivalent of a vegetable would be equal to one ½ c-eq vegetables.
- A food group equivalent of a fruit would be equal to one ½ c-eq fruit.
- A food group equivalent of grain would be ¾ oz-eq whole grain.
- A food group equivalent of dairy would be equal to ¾ c-eq dairy.
- A food group equivalent of protein would:
  - For game meats, such as deer, rabbit, quail, and wild geese, be 1 ½ oz-eq; and
  - For seafood; eggs; beans, peas, and soy products; and nuts and seeds, be 1 oz-eq.

We have divided the protein foods group into these subgroups, which are distinct from the *Dietary Guidelines, 2020–2025* subgroups, as explained further in section V.B.3.b (''Individual foods'').

We are not proposing a food group equivalent for oils, because, as explained in section V.B.3.b (''Individual foods''), we are only proposing that certain oil-based foods meet the criteria for healthy, and oil used in other foods does not contribute to eligibility for bearing the ''healthy'' claim.

These food group equivalents are indicated in table 1.

TABLE 1—FOOD GROUP EQUIVALENTS

Food group and/or subgroup	Food group equivalent
Vegetables	½ cup equivalent vegetable.
Fruits	½ cup equivalent fruit.
Grains	¾ ounce (oz) equivalent whole grain.
Dairy	¾ cup equivalent dairy.
Protein Foods	Game meats.
	1½ oz equivalent.
	Seafood.
	1 oz equivalent.
	Egg.
	1 oz equivalent.
	Beans, peas, and soy products.
	1 oz equivalent.
	Nuts and seeds.
	1 oz equivalent.

As noted in section VI.A (''Overview of Approach''), the c-eq and oz-eq amounts are based on the amounts discussed in the *Dietary Guidelines, 2020–2025.* For vegetables and fruits, a 1 c-eq is: 1 cup raw or cooked vegetable or fruit, 1 cup 100 percent vegetable or fruit juice, 2 cups leafy salad greens, or ½ cup dried fruit or vegetable. For grains, a 1 oz-eq is: ½ cup cooked whole grain rice, whole grain pasta, or cereal; 1 oz dry whole grain pasta or rice; 1 medium (1 oz) slice whole grain bread, tortilla, or flatbread; 1 oz of ready-to-eat whole grain cereal. For dairy, a 1 c-eq is: 1 cup fat-free or low-fat milk, yogurt or lactose-free versions, or fortified soy beverage or yogurt alternatives; 1½ oz natural cheese or 1 oz processed cheese. For protein foods, a 1 oz-eq is: 1 oz game meat or seafood; 1 egg; ¼ cup cooked beans or tofu; 1 tbsp nut or seed butter; ½ oz nuts or seeds (Refs. 1 and 22).

This means, for example, that a ½ cup portion of fresh or frozen green beans and a 1 cup portion of raw spinach would both constitute ½ c-eq vegetables. A ½ cup portion of fresh or frozen fruit, ½ cup portion of 100 percent orange juice, and a ¼ cup portion of raisins (a dried fruit) would all be equal to a ½ c-eq of fruit. A slice of whole wheat bread and a ½ cup portion of cooked brown rice would both be equal to a 1 oz-eq whole grains. A 6-ounce portion of yogurt would be equivalent to ¾ c-eq dairy. An ounce portion of walnuts and 2 tablespoons of peanut butter would be equal to 2 oz-eq of protein foods. A ½ cup portion of black beans would be equal to 2 oz-eq of protein foods (Refs. 1 and 22). Examples of foods and their amounts that meet the food group equivalent requirements are included in a table in the proposed codified language for § 101.65(d)(2).

3. Covered Products

Under proposed § 101.65(3), you may use the term ''healthy'' or related terms (*e.g.,* ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') as an implied nutrient content claim if the food meets the requirements laid out in proposed § 101.65(d)(3)(i)–(vi). These terms are unchanged from the existing regulation at § 101.65(d); see the 1994 ''healthy'' final rule for a more detailed discussion of how these terms were selected (59 FR 24232 at 24235). However, we seek comments on whether there are any other terms synonymous with ''healthy'' that we should consider as we finalize this rulemaking.

Foods that may bear the nutrient content claim ''healthy'' under the proposed updated criteria are broken out into several categories: (1) raw, whole fruits and vegetables; (2) individual food products; (3) combination foods, which encompasses mixed products, main dish products, and meal products; and (4) plain water. The specific requirements for these foods are described in more detail in the following sections.

TABLE 2—ELIGIBLE PRODUCTS FOR ''HEALTHY'' NUTRIENT CONTENT CLAIM

Eligible products for ''healthy'' nutrient content claim	
Product	Criteria for bearing ''healthy'' claim
Raw, whole fruits and vegetables	No additional criteria; all raw, whole fruits and vegetables may bear the claim.
Individual food products	At least 1 food group equivalent per RACC from 1 food group, and Nutrients to limit.
Mixed products	At least ½ food group equivalent each from at least 2 different food groups, and Nutrients to limit.
Main dish as defined at 21 CFR 101.13(m)	At least 1 food group equivalent each from at least 2 different food groups, and Nutrients to limit.
Meal as defined at 21 CFR 101.13(l)	At least 1 food group equivalent each from at least 3 different food groups, and Nutrients to limit.
Water	Plain water and plain, carbonated water may bear the claim.

a. Raw, Whole Fruits and Vegetables

A key objective of the updated criteria is to ensure conformity with current nutrition science and Federal dietary guidance by, among other things, ensuring that the nutrient dense foods recommended by the *Dietary Guidelines, 2020–2025* are eligible to bear the ''healthy'' claim. Precluding such foods from bearing the ''healthy'' claim could undermine an important element of the claim, as the purpose of the healthy claim is to identify foods that, because of their nutrient content, may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance. Healthy dietary patterns described by the *Dietary Guidelines, 2020–2025* include vegetables from all vegetable subgroups (dark green, red and orange, beans, peas, and lentils, starchy, and other) and fruits, especially whole fruits. Vegetables contribute many nutrients to the diet including dietary fiber, potassium, vitamin A, vitamin C, vitamin K, copper, magnesium, vitamin E, vitamin B6, folate, iron, manganese, thiamin, niacin, and choline, while fruits are important contributors of dietary fiber, potassium, and vitamin C. The Dietary Guidelines have consistently emphasized consumption of fruits and vegetables (Ref. 15), and diets high in fruits and vegetables have been associated with specific health benefits, including lower occurrence of coronary heart disease and some cancers (Ref. 16 and 59 FR 24232 at 24244). Despite their importance to a healthy dietary pattern, average intake of vegetables and fruits is below recommended levels among nearly all age-sex groups (Ref. 1).

While we are proposing food group equivalent and nutrient-to-limit requirements for most foods, we are not proposing to subject raw, whole fruits and vegetables to the criteria. For the purpose of this rule, ''raw, whole'' means whole fruits and vegetables that have not been processed, such as whole apples, bananas, or carrots. Raw, whole fruits and vegetables automatically qualify for use of the claim, regardless if they meet the criteria required of other foods. As discussed in the *Dietary Guidelines 2020–2025,* most of the U.S. population (around 80 percent) does not meet the dietary intake recommendation for fruits and an even larger percentage (around 90%) do not meet the intake recommendation for vegetables. Excluding some raw, whole fruits and vegetables from qualifying for the proposed, updated ''healthy'' definition is not supported by scientific evidence or current dietary guidance. Therefore, we tentatively conclude that raw, whole fruits and vegetables do not need to contain a certain amount of fruit or vegetable to contribute to a healthy dietary pattern—for example, a strawberry should be able to bear the ''healthy'' claim even though one strawberry does not constitute a ½ c-eq of fruit. Moreover, raw, whole fruits and vegetables are often sold without packaging or labels. While these products typically do not carry label claims, they may appear on other materials in the stores and elsewhere that may constitute labeling. We therefore tentatively conclude that raw, whole vegetables and fruits should be able to meet the ''healthy'' criteria without meeting a food group equivalent threshold. We seek comment on our tentative conclusions.

We also tentatively conclude that it would be inappropriate to apply nutrient-to-limit criteria to raw, whole vegetables and fruits. For example, sodium and added sugars are not a concern for raw, whole fruits and vegetables because they contain no added ingredients. Furthermore, including a limit for saturated fat would actually *disqualify* certain vegetables, such as whole avocados, which are vegetables containing beneficial nutrients and are sources of unsaturated fat, from meeting the updated ''healthy'' criteria.

For these reasons, we are proposing a narrow exception to the requirements for food group equivalents and nutrients to limit for raw, whole fruits and vegetables. We propose allowing all raw, whole fruits and vegetables to bear the implied nutrient content claim ''healthy,'' without any additional requirements for food group equivalents or nutrients to limit.

We do not propose to include processed fruits and vegetables, such as canned, frozen, dried, or pureed fruits and vegetables, within this exemption, though many may still meet the criteria to bear ''healthy.'' For purposes of this claim, fruits and vegetables that have been cut and packaged for sale, such as cantaloupe pieces cut and packaged for sale in a supermarket are considered processed. We note that fruits and vegetables that have been solely cut and packaged for sale would generally qualify for use of the claim under the criteria for individual foods, as raw fruits and vegetables do not exceed the nutrient criteria and would meet the food group equivalent requirement. For example, plain frozen fruit or vegetables would not exceed the nutrient-to-limit criteria and would meet the food group equivalent requirement. It is possible, though, that there are a few forms of fruit and vegetable products that may have RACCs that are smaller than the size of the required food group equivalent requirement. For example, frozen avocado pieces, specifically, may have a RACC that does not meet the FGE amount criteria of ½ c fruit. We request comment on whether there are any other fruit or vegetable products for which the RACC size may have an impact in terms of qualifying for the claim and we request comment on ways we could address how those products, including frozen avocados, could qualify for the claim. Many processed fruits and vegetables are packaged and sold in a form that makes it appropriate to apply

the food group equivalent requirement to these kinds of food to ensure the product contains a meaningful amount of the fruit and/or vegetable. For example, it is appropriate to require that canned fruit products contain a certain amount of fruit per serving in order to bear the ''healthy'' claim because they contain additional ingredients (*e.g.,* sugar solution) which may impact whether the product has enough fruit per serving to meet the food group equivalent requirement. Furthermore, processed vegetables and fruits may contain other ingredients, such as added sugars or sodium, that can affect their nutrient content; thus, it is necessary to include nutrient-to-limit criteria for such foods. For any type of processed fruits and vegetables where the fruits and vegetables remain primarily unchanged, such as plain frozen fruits and vegetables, those products would generally qualify for use of the claim under the criteria for individual foods, as they do not exceed the nutrient criteria and would meet the food group equivalent requirement. As described in section V.B.3.b (''Individual foods''), we are proposing that individual fruit and vegetable products (including processed fruits and vegetables, but which excludes raw, whole fruits or vegetables) may bear the nutrient content claim ''healthy'' only when they meet certain additional food group equivalent and nutrient-to-limit requirements.

b. Individual Foods

Individual foods are foods that are comprised entirely or almost entirely of one food group (excluding raw, whole fruits and vegetables, as explained above). Foods that contain a meaningful amount (at least half a food group equivalent) of more than one food group would be considered a combination food and are discussed in section VI.B.3.c (''Combination foods''). In many cases, an individual food will be comprised of only one food group; for example, individual foods include oatmeal (which is comprised of only whole grain), dried fruit (fruit), or low-fat plain yogurt (dairy). In some cases, individual foods include ingredients from multiple food groups, but one food group would still predominate, and the product may only contain a minimal amount of another food group; for example, cinnamon raisin oatmeal (primarily whole grain) and yogurt with granola topping (primarily dairy) would both be individual foods. To bear the nutrient content claim ''healthy,'' individual foods would have to meet the criteria outlined in § 101.65(d)(3)(iii), which includes requirements for food group equivalents and for nutrients to limit.

For the purposes of this rule, individual foods have been separated into the six food groups described in the *Dietary Guidelines, 2020–2025:* vegetables, fruits, grains, dairy, proteins (including all subgroups), as well as oils. As in the *Dietary Guidelines, 2020–2025,* individual foods fit into food groups based on how they are consumed, even if this is different from their botanical classification. We are proposing that individual products would need to contain a specified minimum food group equivalent per RACC (*e.g.,* ½ cup of fruit, ¾ cup of dairy) to be labeled ''healthy.'' Individual products would also need to adhere to criteria for nutrients to limit per RACC for saturated fat, sodium, and added sugars. The food group equivalents and the nutrients-to-limit benchmarks are adjusted for each food group. The specific food group equivalent criteria, along with the criteria for nutrients to limit, are discussed further in the following sections.

(1) Vegetable Products

As discussed previously, healthy dietary patterns include vegetables from all vegetable subgroups: dark green, red and orange, beans, peas, and lentils, starchy, and other. The nutrient content of beans, peas, and lentils is similar to foods in both the protein foods group and in the vegetable group and may be counted under either food group. Vegetables contribute many nutrients to the diet including dietary fiber, potassium, and iron, among others, and nutrient contributions can vary across the subgroups (Ref. 21). The *Dietary Guidelines, 2020–2025* notes that each of the food groups and their subgroups provides an array of nutrients and that eating an appropriate mix of foods from the food groups and subgroups is important to promote health at each life stage (Ref. 1). Therefore, consumption of a variety of vegetables from all vegetable subgroups in nutrient-dense forms is encouraged. The vegetables food group can include fresh, frozen, canned, and dried forms of vegetables, as well as 100% vegetable juice. FDA considers concentrated vegetable purees and vegetable pastes to be vegetables for the purpose of calculating food group equivalents since these products are essentially whole vegetables that have been processed to change the physical form of the vegetable to remove moisture. We tentatively do not consider vegetable powders to be vegetables for the purpose of calculating food group equivalents. These products could be produced or used in a way that modifies the whole vegetable to an extent that removes some essential characteristics that are beneficial when consuming the whole vegetable, which could impact nutrient content. However, we recognize that food manufacturers continue to innovate in this space. We welcome comment on whether we should consider certain vegetable powders to be vegetables for the purpose of calculating food group equivalents. In particular, we are interested in any comments or data regarding whether vegetable powders have similar or different nutrient content, or similar or different roles in a healthy dietary pattern, compared to whole vegetables.

The recommended amount of vegetables in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 2½ c-eq of vegetables per day. As described in section VI.B.3.b (''Individual foods''), for most food groups and subgroups, we determined the ''food group equivalent'' by dividing the daily recommended amount by four (for four eating occasions per day). For vegetables, we revised the amount derived from the baseline calculation slightly (from ¾ c-eq down to ½ c-eq) for two reasons. First, vegetables are significantly underconsumed according to the *Dietary Guidelines, 2020–2025.* Second, we found that a ½ c-eq aligned better with the RACCs for most vegetable products as set out in FDA's NFL final rule. Thus, we are proposing that to bear the nutrient content claim ''healthy,'' a vegetable product must contain at least ½ c-eq vegetables per RACC.

We are proposing that the added sugars content for vegetable products must be no greater than 0 percent DV per RACC. This is lower than some other food groups because vegetable products generally do not contain added sugars. We are proposing that vegetable products be subject to the baseline values for sodium and saturated fat; *i.e.,* the sodium content must be no greater than 10 percent DV per RACC and the saturated fat content must be no greater than 5 percent DV per RACC, as many vegetable products in the food supply contain some sodium and added fats for taste, processing, and preservation. We are seeking comment on this proposal.

TABLE 3—VEGETABLE PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Vegetable product	½ cup-equivalent	0% DV	10% DV	5% DV

(2) Fruit Products

Healthy dietary patterns include fruits, especially whole fruits. Fruits contribute many nutrients to the diet, including dietary fiber, potassium, and vitamin C (Ref. 21). Fruits can be consumed in fresh, frozen, canned, and dried forms. FDA considers concentrated fruit purees and fruit pastes to be fruit for the purpose of calculating food group equivalents since these products are essentially whole fruits that have been processed to change the physical form of the fruit to remove moisture. The fruits food group also includes 100 percent fruit juice. We tentatively do not consider fruit powders to be fruits for the purpose of calculating food group equivalents. These products could be produced or used in a way that modifies the whole fruit to an extent that removes some essential characteristics that are beneficial when consuming the whole fruit, which could impact nutrient content. However, we recognize that food manufacturers continue to innovate in this space. We welcome comment on whether we should consider certain fruit powders to be fruits for the purpose of calculating food group equivalents. In particular, we are interested in any comments or data regarding whether fruit powders have similar or different nutrient content, or similar or different roles in a healthy dietary pattern, compared to whole fruits.

The recommended amount of fruits in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 2 c-eq per day. Applying the baseline calculation discussed in section VI.B.3.b (''Individual foods''), we propose that an individual fruit product must contain at least ½ c-eq of fruit per RACC to bear the ''healthy'' claim. We are seeking comment on this proposal.

As with vegetable products, we are proposing to lower the baseline added sugars limit to 0 percent DV per RACC for fruit products. While small amounts of added sugars can be part of a healthy dietary pattern—the *Dietary Guidelines, 2020–2025* recommendations allow for a certain allotment of added sugars per day—we do not want the ''healthy'' claim to encourage addition of added sugars in otherwise nutrient-dense fruit products, which are generally already naturally sweet. Moreover, while we recognize that some fruit juices and canned fruits contain added sugars, the *Dietary Guidelines, 2020–2025* specifically recommends that juices should be 100 percent juice, without added sugars, and that individuals should choose canned fruits that are canned with 100 percent juice or options lowest in added sugars. Thus, to qualify for the ''healthy'' claim, we propose to allow no added sugars in fruit products (which includes products with 100 percent fruit juice). For the fruit category, we find that there are no special circumstances that require deviation from the baseline levels for sodium and saturated fat, so we are proposing the baseline value for sodium of 10 percent DV per RACC and 5 percent DV saturated fat per RACC for fruit products.

TABLE 4—FRUIT PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Fruit product	½ cup-equivalent	0% DV	10% DV	5% DV

(3) Grain Products

Healthy dietary patterns include whole grains and limit the intake of refined grains. Whole grains contain the entire kernel, including the endosperm, bran, and germ. Refined grains differ from whole grains in that the grains have been processed to remove the bran and germ, which removes important nutrients. Whole grains provide nutrients such as dietary fiber, iron, zinc, manganese, folate, magnesium, copper, thiamin, niacin, vitamin B6, phosphorus, selenium, riboflavin, and vitamin A (Ref. 21). Whole grains can be consumed as single foods (*e.g.,* brown rice, oats), or as products that include grains as an ingredient (*e.g.,* breads, cereals, crackers, and pasta).

The recommended amount of grains in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 6 oz-eq per day. At least half of this amount should be whole grains (*i.e.,* at least 3 oz-eq). Whole grains, when prepared with little or no added sugars, sodium, and saturated fat, are typically more nutrient-dense foods and the *Dietary Guidelines, 2020–2025* indicates that whole grains are underconsumed while refined grains are overconsumed. Thus, we propose that grain products must contain whole grains to bear the ''healthy'' claim. Applying the baseline calculation for food group equivalent as explained in section VI.A (''Overview of Approach''), we are proposing that a whole grain equivalent is ¾ oz-eq. This means that to bear the ''healthy'' claim, an individual grain product must contain at least ¾ oz-eq whole grains per RACC. We seek comment on this approach.

For the grains category, we find that there are no special circumstances that require deviation from the baseline levels, so we are proposing the baseline value for all of the nutrients to limit: the added sugars content must be no greater than 5 percent DV per RACC, the sodium content must be no greater than 10 percent DV per RACC, and the saturated fat content must be no greater than 5 percent DV per RACC.

TABLE 5—GRAIN PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Grain product	¾ ounce-equivalent wholegrain	5% DV	10% DV	5% DV

(4) Dairy Products

Dairy in healthy dietary patterns includes fat-free (skim) and low-fat (1 percent) milk, yogurt, cheese, and fortified soy beverages or soy yogurt alternatives. Nutrients provided by foods in the dairy food group include calcium, phosphorus, vitamin A, vitamin D, riboflavin, vitamin B12, protein, potassium, zinc, choline, magnesium, and selenium (Ref. 21). The *Dietary Guidelines, 2020–2025* states that about 90 percent of the U.S. population does not meet dairy recommendations and most individuals would benefit by increasing intake of dairy in fat-free or low-fat forms, whether from milk, yogurt, and cheese, lactose-free versions, or from fortified soy beverages or soy yogurt alternatives. Fat-free and low-fat dairy products provide the same nutrients but less saturated fat (and thus, fewer calories) than higher fat options, such as 2 percent and whole milk and regular cheese.

The *Dietary Guidelines, 2020–2025* includes fortified soy beverages and soy yogurt alternatives in the dairy group because they have similar nutrient compositions and use in meals (Refs. 1, 22). Other products and beverages made from plants (*e.g.,* almond, rice, coconut, oat, and hemp products) are not included in the dairy group because their overall nutritional content is not similar to dairy milk, yogurt, and fortified soy beverages and soy yogurt alternatives (*e.g.,* lower levels of calcium, vitamin D, and other nutrients). However, it is possible that these types of products may eventually be formulated or fortified to have nutritional profiles that are more similar to the nutritional profile of the dairy food group. Although FDA does not generally support fortification as a method to qualify for a ''healthy'' claim, fortification of soy beverage and yogurt alternatives and other plant-based beverage and yogurt alternatives are a special circumstance. As discussed earlier in this rule, around 90 percent of the U.S. population does not meet the dairy recommendations even though dairy is a core element of a healthy dietary pattern. The *Dietary Guidelines, 2020–2025* highlights the importance of increasing overall intake of dairy foods while acknowledging that some individuals are in need of alternative dairy options. For example, lactose-free and low-lactose options are suggested for those with issues in digesting traditional dairy products. For individuals with restrictions on consumption of traditional dairy foods (*e.g.,* medical restrictions or religious preferences), fortified soy beverages and soy yogurt alternatives are included in the dairy group. Including fortified plant-based dairy alternatives among the food options in the dairy group can assist consumers in increasing their dairy intake and meeting the dairy intake recommendations. Therefore, to support the availability of non-dairy choices for individuals who are lactose intolerant or allergic to dairy or choose not to consume dairy, plant-based milk alternatives and plant-based yogurt alternatives whose overall nutritional content is similar to dairy (*e.g.,* provide similar amounts of protein, calcium, potassium, magnesium, vitamin D, and vitamin A) (Ref. 21) and are used as alternatives to milk and yogurt would be evaluated against the dairy criteria for the purposes of the ''healthy'' nutrient content claim.

The recommended amount of dairy in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 3 c-eq per day. Based on our baseline calculations, we are proposing that a food group equivalent of dairy equal ¾ c-eq. This means that an individual dairy food must contain at least ¾ c-eq of dairy per RACC to bear the ''healthy'' nutrient content claim.

We are proposing to increase the saturated fat limit for dairy products from the baseline level. Under the baseline saturated fat limit of 5 percent DV, low-fat dairy (*e.g.,* 1 percent milk) would not meet the criteria for bearing the ''healthy'' claim (Ref. 20). Forms of dairy that are more nutrient dense (*i.e.,* fat-free and low-fat dairy products) provide important nutrients with less saturated fat than 2 percent or whole-fat dairy. As stated above, the *Dietary Guidelines, 2020–2025* therefore recommends increasing intake of dairy products in fat-free and low-fat forms, to replace intake of 2 percent or whole dairy. We are proposing to revise the saturated fat limit for dairy to ≤10 percent DV of saturated fat per RACC to allow low-fat dairy to bear the ''healthy'' claim provided the other proposed criteria are met.

We are also proposing that dairy products (*e.g.,* sweetened yogurt and cheese) must meet the baseline limit for added sugars of 5 percent DV per RACC and for sodium of 10 percent DV per RACC. We find that there are no special circumstances that require deviation from the baseline levels for added sugars and sodium. Additionally, the sodium level of 10 percent is appropriate because many dairy products, especially cheeses, can be expected to contain some sodium due to processing and preservation methods. We seek comment on this approach.

TABLE 6—DAIRY PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Dairy product	¾ cup-equivalent	5% DV	10% DV	10% DV

(5) Protein Food Products

Healthy dietary patterns include a variety of protein foods in nutrient-dense forms, including protein foods from both plant and animal sources. Plant sources of proteins can include nuts, seeds, beans, peas, and lentils, and soy products. The nutrient content of beans, peas, and lentils is similar to foods in both the protein foods group and in the vegetable group and may be counted under either category. Animal sources can include seafood, meat, poultry, and eggs. Along with protein, foods in this group contribute important nutrients such as niacin, vitamin B12, vitamin B6, riboflavin, selenium,

choline, phosphorus, zinc, copper, vitamin D, and vitamin E and iron (Ref. 21). Additionally, seafood can provide polyunsaturated omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid). While Americans' overall intakes of protein foods are close to the recommended amounts, many Americans do not meet the intake recommendations for specific protein subgroups. Therefore, the *Dietary Guidelines, 2020–2025* recommends shifts within the protein group to add variety to the intake of protein foods (Ref.1).

Since specific considerations for different foods within the protein foods group may vary, we are proposing to divide protein foods into the following subgroups: (1) game meats; (2) seafood; (3) eggs; (4) beans, peas, lentils, and soy products; and (5) nuts and seeds. These subgroups are slightly different from the subgroups in the *Dietary Guidelines, 2020–2025* because they are based on what we determined as the specific needs for variation in food group equivalents and the nutrients to limit, as discussed below. In addition, our subgroups do not include the animal sources of protein whose labeling is regulated by USDA's Food Safety and Inspection Service (*e.g.,* meat and poultry products, egg products, and catfish).

The recommendation for protein foods in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 5½ ounce-equivalents per day. As with all of the food groups, we calculated the food group equivalent using the method described in section VI.B.3.b (''Individual foods''). One fourth of 5½ oz equivalents is 1⅜ oz equivalents and based on standard rounding rules, we propose that the food group equivalent criteria for game meat is at least 1½ oz equivalent. We propose rounding down to 1 oz-eq for all other protein subgroups. For beans, peas, lentils, soy products, and seafood, we propose rounding down to increase the number of products containing these subgroups that would be eligible to bear the claim, and therefore encourage consumption of them. This is consistent with the Dietary Guidelines, 2020–2025 strategy to increase variety of choices made by replacing some meats, poultry, and egg intake with seafood, beans, peas, and lentils, nuts, seeds, and soy products. Game meat, which is part of the traditional diets of certain populations, falls within the meat, poultry, and egg protein subgroup in the Dietary Guidelines. However, we acknowledge that intake levels of game meat may not be at similar levels as other meat, poultry and egg products. We also propose rounding down to at least 1 oz-eq for eggs as this is equal to one egg, a common serving size. We welcome comments on the values set for the food group equivalents for the protein subgroups.

For all of the protein food subgroups, we propose that the food contain no more than 0 percent DV of added sugars per RACC because most protein food products generally do not contain added sugars. We are also proposing that all protein products must meet the baseline limit for sodium of 10 percent DV per RACC as many protein products in the food supply contain some sodium for taste, processing, and/or preservation.

Because protein foods are a diverse group of foods containing varying amounts of saturated fat, we are proposing different saturated fat limits for some subgroups. For game meats, seafood, and eggs, we are proposing to increase the limit for saturated fat to 10 percent DV because using the baseline saturated fat limit would prevent these foods from being able to bear the ''healthy'' claim even though they contain important nutrients that may help consumers maintain healthy dietary practices. The *Dietary Guidelines, 2020–2025* recommends shifting to nutrient-dense options when selecting protein foods, specifically lean and low-fat options. We propose a ≤10 percent DV saturated fat limit for game meat, which is similar to the <2 g per RACC saturated fat limit for the ''extra lean'' nutrient content claim for seafood or game meat products (§ 101.62(e)(4)) as is used in the current criteria for ''healthy.'' Seafood provides important nutrients, such as beneficial fatty acids (*e.g.,* eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)). The *Dietary Guidelines, 2020–2025* encourages consumption of seafood but note that almost 90 percent of Americans do not meet that recommendation and that protein foods are generally consumed in forms with higher amounts of saturated fat or sodium. Thus, the *Dietary Guidelines, 2020–2025* recommends replacing processed or high-fat meats with seafood to help lower intake of saturated fat and sodium (Ref. 1). We propose a ≤10 percent DV saturated fat limit for seafood consistent with § 101.62(e)(4) and because seafood contains beneficial nutrients that make it part of a healthy dietary pattern.

We are also proposing an adjustment for eggs. As mentioned previously, the *Dietary Guidelines, 2020–2025* recommends increasing variety in protein food choices in order to meet the recommendations for specific protein subgroups. Eggs are considered a nutrient dense protein food option, particularly compared with some protein foods that typically have high levels of saturated fat and sodium (*e.g.,* sausages). While about three-quarters of Americans meet the recommendation for the meat, poultry, and eggs subgroup, eggs provide choline and vitamin D, two nutrients with notably low intakes (Ref. 1). As noted above, using the baseline limit of 5 percent DV of saturated fat per RACC would prevent eggs from being able to bear the ''healthy'' claim, so we are also proposing to raise the saturated fat limit for eggs to ≤10 percent DV per RACC. Beans, peas, and lentils and soy products are inherently low in saturated fat; therefore, we are proposing the baseline value for saturated fat of ≤5 percent DV per RACC for these foods.

We are also proposing that the saturated fat content of nuts and seeds does not contribute toward the overall saturated fat limit for nut and seed products, which would be the baseline value of ≤5 percent DV per RACC. Unsalted nuts and seeds are considered nutrient dense protein foods due to their nutrient content (*e.g.,* they provide important nutrients such as unsaturated fatty acids and vitamin E). While nuts and seeds contain saturated fat, they have a fat profile makeup of predominantly monounsaturated and polyunsaturated fats. Numerous studies have demonstrated that replacing other sources of saturated fat in the diet with nuts has beneficial effects on cardiovascular disease risk, including nuts with higher saturated fat content (Refs. 22 and 33). Based on the scientific evidence, FDA has qualified health claims characterizing the relationship between the consumption of nuts and a reduced risk of coronary heart disease, including a qualified health claim for macadamia nuts which are relatively higher in saturated fat than other nuts. More than half of Americans do not meet the recommendation for nuts, seeds, and soy products, and the *Dietary Guidelines, 2020–2025* recommends consuming nuts without differentiating among types and the saturated fat content of nuts is variable. The *Dietary Guidelines, 2020–2025* also recommends reducing saturated fat by substituting certain ingredients with sources of unsaturated fats, including using nuts and seeds in a dish instead of cheese (Ref. 1). If nuts' and seeds' saturated fat content contributed to the overall baseline saturated fat value of ≤5 percent DV per RACC, then most nuts and seeds would be prevented from meeting the ''healthy'' definition (Ref. 20). Even increasing the allowable level

of saturated fat to levels twice as much (10 percent DV) would prevent some nuts and seeds, such as macadamia nuts, from being eligible for the ''healthy'' claim, despite the science supporting their beneficial impact on cardiovascular health. As mentioned above, the saturated fat content of nut and seed varieties vary. However, excluding specific types of nuts and seeds from being eligible for the claim would be inconsistent with the scientific evidence demonstrating a beneficial effect of nut consumption on health outcomes, which is the basis for current dietary recommendations that nuts and seeds are part of a healthy dietary pattern. We therefore propose that, for nut and seed products, the saturated fat from the nuts and seeds do not contribute toward the overall saturated fat limit. For example, a peanut butter product may contain peanuts and vegetable oil. In this example, both the peanuts and vegetable oil contain saturated fats. However, the saturated fat from the peanuts would not contribute to the saturated fat limit of ≤5 percent DV per RACC; only the saturated fat from the vegetable oil would contribute to the limit. Therefore, if the saturated fat from the vegetable oil is ≤5 percent DV of the RACC, then the peanut butter would meet the saturated fat limit. Additionally, if a product only contained nuts, such as a jar of raw, unsalted peanuts, the product would not be subject to a saturated fat limit in order to bear the ''healthy'' claim.

We seek comment on whether nuts with relatively higher amounts of saturated fat should be eligible for the ''healthy'' claim.

TABLE 7—PROTEIN PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Game meat	1½ oz equivalent	0% DV	10% DV	10% DV.
Seafood	1 oz equivalent	0% DV	10% DV	10% DV.
Egg	1 oz equivalent	0% DV	10% DV	10% DV.
Beans, peas, and soy products	1 oz equivalent	0% DV	10% DV	5% DV.
Nuts and seeds	1 oz equivalent	0% DV	10% DV	5% DV (excluding saturated fat derived from nuts and seeds).

(6) Oils

While oils are not technically a food group in the *Dietary Guidelines, 2020–2025,* the *Dietary Guidelines, 2020–2025* emphasizes oils as part of a healthy dietary pattern because they are a common characteristic of dietary patterns associated with positive health outcomes and provide essential fatty acids (Ref. 1). As part of its focus on shifts—that is, choosing nutrient-dense foods and beverages in place of less healthy choices, rather than increasing intake overall—the *Dietary Guidelines, 2020–2025* recommends cooking with vegetable oil in place of fats high in saturated fat (such as butter, shortening, lard, and coconut oil) as a strategy to shift intake.

We propose including 100 percent oils, oil-based spreads, and oil-based dressings in the definition of ''healthy'' where they meet certain specified requirements. While the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level recommends 27 g (about 5 teaspoons) per day of oils, we are not proposing that oil products contain a certain *quantity* of oil in order to be labeled healthy. This is because the *Dietary Guidelines, 2020–2025* does not recommend high consumption of oil, but instead that oils be used instead of fats high in saturated fats while staying within daily calorie limits. The proposed requirements for oils, oil-based spreads, and oil-based dressings are discussed in further detail in this section.

Under proposed § 101.65(d)(2)(iii)(F)(*1*), for 100 percent oils to bear the ''healthy'' claim, they would have to contain only oil, which means they would contain no sodium or added sugars. For the 100 percent oil subcategory, we are proposing a limit of saturated fat of ≤20 percent of total fat. The *Dietary Guidelines, 2020–2025* emphasizes oils, such as canola, corn, olive, and sunflower oils, as part of a healthy dietary pattern because of their fatty acid profile. However, the *Dietary Guidelines, 2020–2025* specifically does not include the fat from some tropical plants, such as coconut oil, palm kernel oil, and palm oil, in the category of oils because they contain a higher percentage of saturated fats than other oils. We propose the 20 percent limit on saturated fat to ensure that only oils with a fat profile of predominantly monounsaturated and polyunsaturated fats, as recommended by the *Dietary Guidelines, 2020–2025,* meet the criteria for ''healthy.'' The proposed 20 percent limit is consistent with the percentage used by the National Academies to describe dietary fats low in saturated fatty acids (Ref. 7). This 20 percent saturated fat limit is also consistent with the saturated fat requirement for determining the type of foods that are eligible to bear the claim on the ''Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease'' (Docket No. FDA–2007–Q–0291). Thus, we propose a 20 percent limit on saturated fat in oils to bear the nutrient content claim ''healthy.''

We also propose allowing oil-based spreads, such as tub margarine, to bear the claim ''healthy'' when they meet certain requirements. Use of spreads made with vegetable oils can help shift intake away from other fats high in saturated fat. The *Dietary Guidelines, 2020–2025* recommends cooking and purchasing products made with oils higher in polyunsaturated and monounsaturated fats rather than using butter, shortening, or coconut or palm oils (Ref. 1). Thus, we propose allowing oil-based spreads to qualify only when their fat content comes solely from oils and where the product's overall saturated fat content is no more than 20 percent of total fat. For such spreads, we are proposing a limit for added sugars of 0 percent DV per RACC, as these products are not expected to contain added sugars. We are also proposing to lower the sodium limit to 5 percent DV per RACC for spreads, due to their small RACCs. This approach is reasonable given that many of these products already contain less than 5 percent DV of sodium per RACC (Ref. 20). We seek comment on the proposed criteria for oil-based spreads, particularly on whether the proposed saturated fat criteria would adequately ensure that spreads that are part of a healthy dietary pattern (because they are lower in saturated fat and higher in unsaturated fatty acids, consistent with current nutrition science and Federal dietary

guidance) are eligible to bear the ''healthy'' nutrient content claim.

We also propose allowing oil-based dressings to bear the claim ''healthy'' when they meet certain requirements. Similar to oil-based spreads, use of dressings made with vegetable oils can help shift intake away from use of dressings made with fats that are high in saturated fat. For oil-based dressings to bear the claim ''healthy,'' we are proposing they must contain at least 30 percent oil, which is consistent with the oil content in the standard of identity for salad dressing (21 CFR 169.150). Dressings must be made from oils that meet the requirements in § 101.65(d)(2)(ii)(F)(*1*) (*i.e.,* saturated fat level of the oil must be ≤20 percent of total fat).

We are proposing that oil-based dressings be permitted to contain up to 2 percent DV of added sugars per RACC. Many dressings contain a small amount of added sugars. We are proposing to allow a small amount of added sugars because dressings are typically consumed with vegetables, another highly recommended and underconsumed food group. We are also proposing a sodium limit of ≤5 percent DV per RACC for dressings, due to their small RACCs. As with spreads, this approach is reasonable given that many of these products already contain less than 5 percent DV of sodium per RACC (Ref. 20). Finally, we propose that the dressings must meet a saturated fat limit of ≤20 percent of total fat. We seek comment on the proposed criteria for oil-based dressings; in particular, we seek comment on whether the proposed 30 percent oil level is an appropriate requirement for oil-based dressings, and on whether the proposed saturated fat criteria adequately ensure that dressings that are part of a healthy dietary pattern because they are lower in saturated fat and higher in unsaturated fatty acids, consistent with current nutrition science and Federal dietary guidance, are eligible to bear the ''healthy'' claim.

TABLE 8—OIL PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
100% Oil	N/A	0% DV	0% DV	20% of total fat.
Oil-based Spreads	N/A	0% DV	5% DV	20% of total fat.
Oil-based Dressing (must contain at least 30% oil and saturated fat level of the oil must be ≤20 percent of total fat).	N/A	2% DV	5% DV	20% of total fat.

c. Combination Foods

(1) Overview

As explained previously, individual foods are foods that are primarily comprised of one food group. In some cases, individual foods can contain ingredients from multiple food groups, but not in high enough quantities to equal a food group equivalent in more than one food group. These types of foods are subject to the proposed requirements in section VI.B.3.b (''Individual foods''). However, many foods on the market contain multiple ingredients in combinations more complex than those that would fit in the individual food groups. For purposes of this rule, we refer to these foods as ''combination foods.'' Combination foods are comprised of meaningful amounts of more than one food group as described in more detail in the next few paragraphs, and therefore are subject to different criteria in order to bear the nutrient content claim ''healthy.''

The *Dietary Guidelines, 2020–2025* food group recommendations are discussed in section V.A (''Overview of Approach''). In that section, we discussed the daily intake recommendations of each of the food groups and subgroups (vegetables, fruits, grains, dairy, and protein foods) in the ''Healthy U.S.-Style Dietary Pattern,'' and explained that we are proposing that individual foods must contain at least one food group equivalent to be eligible for ''healthy.'' We propose similar requirements for combination foods, taking into account the varying composition of food groups and subgroups they contain. The nutrients-to-limit criteria for combination foods are also based on the criteria for individual foods, depending on the number of food group servings contained in the combination food. The food group equivalent and nutrients-to-limit requirements for combination foods are discussed in more detail below.

We are proposing different criteria for combination foods depending on their role in the diet, which we have categorized into mixed products, main dish products, and meal products:

- *Mixed products* are similar in size to an individual food but contain more than one food group. For example, a mixed product could include a granola product that is half whole grains and half nuts. We are proposing to require that a mixed product contain at least half a food group equivalent each of two different food groups per RACC. We are also proposing nutrients-to-limit requirements that reflect the food group composition of mixed products.
- *Main dish products,* defined at § 101.13(m), are larger in size (weighing at least 6 oz per labeled serving) than individual foods and mixed products, and are intended to make a major contribution to a meal. A main dish product might include, for example, a frozen entrée that is intended to be eaten with additional items to form a full meal. Because of their size and purpose in the diet, we are proposing to require that main dish products contain at least a food group equivalent each of two different food groups per labeled serving. We are also proposing specific nutrients-to-limit criteria to take into account their purpose in the diet and their larger RACCs.
- *Meal products,* defined at § 101.13(l), are larger in size (weighing at least 10 oz per labeled serving) than main dish products, and are intended to comprise all of the food for a single eating occasion (*i.e.,* a full meal). An example of a meal would be a frozen dinner. Because of their size and purpose in the diet, we are proposing to require that meal products contain at least a food group equivalent each from three different food groups per labeled serving. We are also proposing nutrient-to-limit criteria to take into account their purpose in the diet and their larger RACCs.

(2) Additional considerations for combination foods

There are a few special considerations that apply to all combination foods. First, under the proposed criteria for combination foods, oils do not count as a food group equivalent. This is because oils are not considered a food group under the *Dietary Guidelines, 2020–2025,* but instead an element that should be included in a healthy dietary

pattern as a substitute for fats high in saturated fat. Individual oil products that are eligible to bear the ''healthy'' claim include 100 percent oil products, oil-based spreads, and oil-based dressings. This category does not include oils as an ingredient in formulated foods (*e.g.,* foods fried in a vegetable oil). Thus, under the proposed criteria for combination foods, oils are not considered a food group equivalent. This does not mean that combination foods cannot contain oils and still qualify for the ''healthy'' claim; it means that such oils do not contribute to the food group equivalent requirements in order to meet the criteria to be labeled ''healthy.'' We are proposing saturated fat limits for combination foods to help encourage the use of healthy oils instead of fats high in saturated fat in combination foods.

Second, similar to the criteria for individual foods, we are proposing that the saturated fat from nuts and seeds does not contribute toward the saturated fat limit for nut and seed products. This is because nuts and seeds are nutrient dense foods and consumption of nuts and seeds has been found to be beneficial to health despite the fact that some varieties contain levels of saturated fat that exceed the limits set for other protein foods. Based on the scientific evidence demonstrating beneficial effects of nut consumption, FDA has multiple qualified health claims for nuts, and consumption of nuts and seeds is encouraged by the *Dietary Guidelines, 2020–2025,* as discussed in more detail in the individual foods section. Therefore, to make the criteria for combination foods consistent with the criteria for individual foods, we are proposing that when nuts and seeds are included as ingredients in combination foods, the saturated fat contained in the nuts and seeds does not contribute toward the saturated fat limit. For example, for a mixed product that contains one half serving of nuts and one half serving of whole grains, the food would have a saturated fat limit of 5 percent DV, but the saturated fat from nuts and seeds would not contribute to this limit.

Finally, we are proposing that beans, peas, and lentils may be counted as either a protein food or as a vegetable in a combination food. As noted previously, beans, peas, and lentils (which include foods such as kidney beans, pinto beans, white beans, black beans, garbanzo beans, lentils, and split peas) are considered both vegetables and protein foods in the *Dietary Guidelines, 2020–2025,* because their nutrient content is similar to both protein foods and to vegetables. Consistent with the *Dietary Guidelines, 2020–2025,* we propose that beans, peas, and lentils may count as either a vegetable or a protein food in a combination food for purposes of food group equivalent criteria. If a combination food has more than one type of food from the beans, peas, and lentils subgroup, in amounts such that each food meets the food group requirements individually, the amount of one food from the beans, peas, and lentils subgroup can meet the vegetable group requirement while another food from the same subgroup can be used to meet the protein food requirement. However, if the food product has only one type of food from the beans, peas, and lentils subgroup, the one type cannot count toward both the vegetable and protein food group requirements in the same combination food. For example, if a food product had a ½ cup of split peas and a ½ cup of black beans, the black beans could be counted as one food group equivalent of protein foods and the split peas as one food group equivalent of vegetables in a combination food. However, if a food product had one cup only of black beans, it could be counted as one food group equivalent of vegetables or one food group equivalent of protein foods, but not as both.

(3) Combination foods criteria.

In addition to the special considerations just described, we are proposing specific criteria for food group equivalents and nutrients to limit for mixed products, main dishes, and meals. These criteria are detailed in the following sections.

(i) Mixed products—Mixed products are foods that contain multiple ingredients but do not contain a full food group equivalent per RACC of any single *Dietary Guidelines, 2020–2025* food group. A mixed product could include, for example, a trail mix that contains fruit and nuts, where neither of these components are in sufficient quantities to equal a full food group equivalent. Where a product contains more than one food group and does not contain a full food group equivalent of any one food group, we are proposing that it can bear the ''healthy'' claim if it contains a sufficient amount from two different food groups. Specifically, we propose that a mixed product must contain at least half of a food group equivalent each of two different food groups per RACC. The amount in a food group equivalent is specified in proposed § 101.65(d)(2)(ii). For example, the aforementioned trail mix could meet the food group equivalent requirement if it contains ¼ c-eq fruit (half a fruit food group equivalent) and ½ oz-eq nuts (half a food group equivalent of nuts and seeds). One food group equivalent equals ¼ of the total daily recommended amount of each of the recommended food groups. For individual foods we have set a minimum amount of one full FGE. For mixed products, we reduce this amount to half of a food group equivalent in order to allow multi-component foods, that contribute to meeting the daily recommended amounts of food groups, to bear a ''healthy'' claim. For consumers who use the ''healthy'' claim in constructing their diets, mixed products bearing a ''healthy'' claim that contain less than half of a food group equivalent may make it difficult for consumers to meet their total daily amounts of recommended food groups. However, we request comments on whether lower amounts of food group equivalents (*e.g.,* ¼ FGE) would be similarly effective as ½ FGE in helping consumers meet their total daily amounts of recommended food groups for multicomponent foods.

We also propose that mixed products would have to meet certain nutrients-to-limit criteria to bear the ''healthy'' claim. Because they contain at least two half food group equivalents, mixed products contain an overall food group equivalent similar to that of individual foods. We calculated the nutrients-to-limit criteria for mixed products by finding the average of the nutrients to limit for their component food groups. For example, for a mixed product that contains a half food group equivalent of dairy and a half food group equivalent of fruit, the added sugars limit would be 2½ percent DV per RACC (the average of 5 percent DV for dairy and 0 percent DV for fruit), sodium limit would be 10 percent DV per RACC (as both food groups have the same sodium limit), and the saturated fat limit would be 7½ percent DV per RACC (the average of 10 percent DV for the dairy and 5 percent DV for the fruit). Because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein also varies depending on the type of protein in the product. The proposed nutrients to limit criteria per RACC for each type of mixed product are reflected in table 9.

TABLE 9—MIXED PRODUCT REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
½ FGE fruit, vegetable, or protein + ½ FGE fruit, vegetable, or protein.	0% DV	10% DV	5% DV or 7½% DV if the protein is game meat, seafood, or egg.
½ FGE whole grain + ½ FGE fruit, vegetable, or protein.	2½% DV	10% DV	5% DV or 7½% DV if the protein is game meat, seafood, or egg.
½ FGE dairy + ½ FGE fruit, vegetable, or protein	2½% DV	10% DV	7½% DV or 10% DV if protein is game meat, seafood, or egg.
½ FGE dairy + ½ FGE whole grain	7½% DV	10% DV	7½% DV.

(ii) Main dish products—A main dish product is defined by our regulations at § 101.13(m) as a food that makes a major contribution to a meal by weighing at least 6 oz per labeled serving; and containing not less than 40 g of food, or combinations of foods, from each of at least two food groups (as specified in § 101.13(m)(1)(ii)). In addition to the food group requirements, the product must be represented as, or in a form commonly understood to be, a main dish (*e.g.,* not a beverage or dessert). Such representations may be made either by statements, photographs, or vignettes.

Main dish products are food products of significant size intended to contain most of the components of a meal. Because of their size and purpose in the diet, we propose that these types of food products must contain at least one food group equivalent each of two different food groups or subgroups as specified by proposed § 101.65(d)(2)(ii). These food group requirements are different and distinct from the food groups specified in § 101.13(m)(1)(ii). In particular, fruits and vegetables are two separate food groups for the purposes of the ''healthy'' claim (where they are one combined food group under § 101.13(m)(1)(ii)), consistent with the *Dietary Guidelines, 2020–2025.* An example of a main dish product that might bear the ''healthy'' claim would be a vegetable lasagna product that contains a ½ c-eq of mixed vegetables (vegetable food group equivalent) and ¾ oz-eq of whole grains (whole grain equivalent) per labeled serving.

Main dish products would also be subject to specific nutrients-to-limit criteria, which would apply per labeled serving. We calculated the nutrients-to-limit criteria for main dish products by adding together the nutrient limits for the two individual food groups that make up the main dish. For example, for the vegetable lasagna main dish, the added sugars limit would be 5 percent DV (5 percent DV for whole grains plus 0 percent DV for vegetables), the sodium limit would be 20 percent DV (10 percent DV for whole grains plus 10 percent DV for vegetables), and the saturated fat limit would be 10 percent DV (5 percent DV for whole grains plus 5 percent DV for vegetable).

As with mixed products, because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein foods also varies depending on the protein subcategory in the product. For example, a main dish containing salmon and brown rice would have a higher saturated fat limit (15 percent DV) than a main dish containing tofu and brown rice (10 percent DV). The proposed nutrients to limit criteria per labeled serving for each type of main dish product are reflected in table 10.

TABLE 10—MAIN DISH REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	0% DV	20% DV	10% DV or 15% DV if the protein is game meat, seafood, or egg.
1 FGE whole grain + 1 FGE fruit, vegetable, or protein.	5% DV	20% DV	10% DV or 15% DV if the protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE fruit, vegetable, or protein	5% DV	20% DV	15% DV or 20% DV if protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE whole grain	10% DV	20% DV	15% DV.

(iii) Meal products—A meal product is defined by our regulations at § 101.13(l) as a food that makes a major contribution to the total diet by weighing at least 10 oz per labeled serving and containing no less than three 40 g portions of food, or combinations of foods, from two or more of the food groups specified at § 101.13(l)(1)(ii). In addition to the food group contribution requirements, the product must be represented as, or must be in a form commonly understood to be, a breakfast, lunch, dinner, or meal. As with main dishes, such representations may be made either by statements, photographs, or vignettes.

For a meal product to be eligible to bear the ''healthy'' claim, we propose in § 101.65(d)(3)(iv) that it must contain at least one full food group equivalent each of three different food groups or subgroups specified by the proposed regulation in § 101.65(d)(2)(i) through (iv) (vegetable, fruit, whole grain, dairy, or protein foods) per labeled serving. As with main dish products, these food group requirements are different and distinct from the food groups in § 101.13(l)(1)(ii). An example of a meal product containing the necessary food group equivalents to bear the ''healthy'' claim would be a frozen salmon dinner containing 1 oz-eq salmon, ½ c-eq green beans, and ¾ oz-eq brown rice, representing a food group equivalent each of seafood (protein food), vegetables, and whole grains.

As with mixed products and main dish products, meal products would also be subject to specific nutrients-to-limit criteria, which would apply per labeled serving. The nutrients-to-limit criteria for meals are the sum of the requirements for the three individual food groups that comprise the meal. For example, in the salmon meal, the added

sugars limit would be 5 percent DV (0 percent DV for vegetable, 0 percent DV for seafood, and 5 percent DV for whole grain), the sodium limit would be 30 percent DV (10 percent DV each for vegetable, seafood, and whole grain), and the saturated fat limit would be 20 percent DV (5 percent DV for vegetable, 10 percent DV for seafood, and 5 percent DV for whole grain).

As with mixed products and main dish products, because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein foods also varies depending on the protein subcategory in the product. The proposed nutrients-to-limit criteria per labeled serving for each type of meal product are reflected in table 11.

TABLE 11—MEAL PRODUCT REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	0% DV	30% DV	15% DV or 20% DV if the protein is game meat, seafood, or egg.
1 FGE whole grain + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	5% DV	30% DV	15% DV or 20% DV if the protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	5% DV	30% DV	20% DV or 25% DV if protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE whole grain + 1 FGE fruit, vegetable, or protein.	10% DV	30% DV	20% DV or 25% DV if the protein is game meat, seafood, or egg.

(iv) Water—We are proposing to include plain and plain, carbonated water in the updated definition of ''healthy.'' According to the National Academies (Ref. 23), water is the largest single constituent of the human body and is essential for cellular homeostasis and life. It provides the solvent for biochemical reactions, is the medium for material transport, and has unique physical properties (high specific heat) to absorb metabolic heat. Water is essential to maintain vascular volume, to support the supply of nutrients to tissues, and to remove waste. Body water deficits challenge the ability of the body to maintain homeostasis during perturbations (*e.g.,* sickness, physical exercise, or climatic stress) and can impact function and health (Ref. 23). The total water intake needed to prevent the deleterious effects of dehydration comes from drinking water, water in other beverages, and water (moisture) in food. Approximately 80 percent of total water intake comes from drinking water and other beverages.

Water itself is not categorized under a recommended food group in the *Dietary Guidelines, 2020–2025.* However, water is emphasized in the *Dietary Guidelines, 2020–2025* beverage recommendations. The *Dietary Guidelines, 2020–2025* recommends that the ''primary beverages consumed'' should be ''beverages that are calorie-free—especially water—or that contribute beneficial nutrients, such as fat-free and low-fat milk and 100 percent fruit juice'' (Ref. 1). Organizations, such as the National Academy of Medicine, and public health agencies, such as the Centers for Disease Control and Prevention, widely recognize the benefits of water, that it is a preferred source of hydration, and is necessary for proper functioning of the human body, and, accordingly, recommend increased availability of drinking water (Refs. 24–26).

Under the existing regulation at § 101.65(d), water cannot be labeled ''healthy'' because it does not meet the existing nutrient-related criteria. Beverages included in a healthy dietary pattern, such as water, are those that allow nutrient needs to be met through the dietary pattern by allowing consumers to meet the food group recommendations without exceeding calorie needs. Thus, consideration of water under the ''healthy'' claim is appropriate as water is an important beverage for maintaining healthy dietary practices due to its nutrient content and how the profile affects the overall dietary pattern. Further, the *Dietary Guidelines, 2020–2025* recommends making shifts toward healthier food and beverage choices, such as choosing water in the place of sugar-sweetened beverages and emphasize choosing nutrient-dense foods to help achieve healthy dietary patterns within calorie limits. To help achieve this, the *Dietary Guidelines, 2020–2025* further recommends limiting added sugars in the diet, since a healthy dietary pattern within calorie limits is difficult to achieve when added sugars exceed 10 percent of calories. The major source of added sugars in the typical U.S. diet is beverages, including sugar-sweetened beverages and sweetened coffees and teas, which account for 35 percent of all added sugars consumed by the U.S. population (Ref. 1). Thus, the absence of added sugars is particularly relevant to inclusion of water when defining the implied nutrient content claim ''healthy.'' Further, the *Dietary Guidelines, 2020–2025* recommends selecting calorie-free beverages, such as water, to help achieve a healthy dietary pattern within calorie limits.

In addition, the *Dietary Guidelines, 2020–2025* specifically calls out water, 100 percent fruit juice, and fat-free/low-fat milk as beverages to consume in a healthy dietary pattern. As discussed previously, 100 percent vegetable juice, 100 percent fruit juice, and fat-free and low-fat milk are eligible to bear the nutrient content claim ''healthy'' under this proposed rule; therefore, it would be consistent with a healthy dietary pattern to also allow water to bear the ''healthy'' claim. Moreover, the *Dietary Guidelines, 2020–2025* recommends water without restriction, in contrast to milk and 100 percent juice beverages, which should be consumed in the context of the recommended intake amounts of each individual food group and within calorie limits.

Based on these considerations, we propose including plain water—both still and carbonated—in the definition of ''healthy.'' We seek comment on whether water should be included in the definition, and whether ''water'' should be expanded, for example, to include waters containing non-caloric flavors or other non-caloric ingredients. In addition, because only labeled water (*e.g.,* bottled water) would commonly bear the ''healthy'' claim, we also seek comment on whether allowing bottled water to be labeled ''healthy'' could potentially lead some consumers to believe that bottled water is healthier than tap water. Beyond water, the *Dietary Guidelines, 2020–2025* states that beverages that are calorie-free should be primary beverages consumed and that coffee and tea with little, if any, sweeteners or cream are also beverage options that can be part of a healthy

dietary pattern. Therefore, we also seek comment on the eligibility of calorie-free beverages, coffee, and tea to bear the ''healthy'' claim.

4. Records Requirements

We are proposing limited recordkeeping requirements on manufacturers to facilitate FDA's ability to verify compliance with certain aspects of the proposed rule. See section V. (''Legal Authority'') for the discussion of our legal authority for proposing recordkeeping and records access requirements. Compliance with the requirements for nutrients to limit will be verifiable for all food products using the Nutrition Facts Label; that is, it will be apparent from the Nutrition Facts Label whether a food meets the applicable criteria for saturated fat, sodium, and added sugars content, and thus no additional records are required. For some foods, we will also be able to use the product label (including the Nutrition Facts Label, the ingredient list, the statement of identity, and any other information) to verify compliance with the food group requirements. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100 percent oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetable food group) to bear the ''healthy'' claim.

However, for certain foods bearing the ''healthy'' claim, the label will not be sufficient to verify that the food meets the requirements for ''healthy'' as described in § 101.65(d)(3). Specifically, the label will not provide sufficient information for FDA to verify that certain foods containing multiple components (such as most grain products and all combination foods) meet the food group equivalent requirements to bear the claim. For these foods, we are proposing to require recordkeeping to demonstrate compliance with the food group equivalent requirements, given the nature of the information necessary to determine compliance and the number of foods potentially affected. We are proposing to require the manufacturer of a food bearing the implied nutrient content claim ''healthy'' to make and keep records, identified in proposed § 101.65(d)(4), where the food group equivalent(s) is/are not apparent based on the label of the food. These records would verify that the food bearing the ''healthy'' claim meets the food group equivalent requirements. This recordkeeping requirement would not apply to water or to raw, whole fruits and vegetables, which do not have food group equivalent requirements.

This recordkeeping requirement would always apply to manufacturers of mixed products, main dish products, and meal products, as these products contain multiple components and it will not be clear how much of each food group is contained in the products without additional information. For individual foods, it will depend on the food whether such records are required. For example, a manufacturer of a multigrain bread containing both whole wheat and refined wheat flours would be required to keep records under this section. This is because it would not be apparent based on the label whether a serving of the bread contains at least ¾ oz-equivalent of whole grains. By contrast, a manufacturer would *not* be required to keep such records for a 100 percent whole wheat bread, because the ingredient statement on the information panel would indicate that the bread contains *only* whole-grain flour, and therefore, it would be apparent from the label that the bread contains the required ¾ oz-eq of whole grains (as one slice of whole wheat bread would be a 1 oz-eq of whole grains). Other examples of individual foods that would not be subject to the recordkeeping provision include dried fruit, plain yogurt, and brown rice.

Where the proposed requirements cannot be verified using the label, only the manufacturer will have the information required to determine whether the product meets the food group equivalent requirements for bearing the ''healthy'' claim. The information contained in manufacturers' records is an accurate and practical method for ensuring that the nutrient content claim is used in accordance with § 101.65(d) and that the food labeling complies with section 403(r) of the FD&C Act. We tentatively conclude that the records will provide FDA with the necessary means to determine compliance with the food group equivalent requirements for bearing the ''healthy'' nutrient content claim.

Manufacturers will be responsible for the type of records they maintain and are not required to produce any specific form or document. The manufacturer is in the best position to know which of its records provide the documentation required to determine compliance. Records used to verify that a food meets the food group equivalent requirements for ''healthy'' could include recipes or formulations, batch records providing data on the weight of certain ingredient contributions to the total batch, certificates of analysis from ingredient suppliers, or other appropriate verification documentation that provides the needed assurance that a food bearing the ''healthy'' claim complies with the food group equivalent requirements. We expect that manufacturers choosing to use the ''healthy'' claim will have the type of records needed to verify that the food meets the requirements, given that they will have to analyze their product to determine whether it meets the requirement in order to bear the claim. The proposed records requirement is intended to provide flexibility in what records the manufacturer makes available to FDA to verify the claim. The records provided during an inspection by FDA would only need to provide information on the food group equivalents because the information on nutrients to limit will be available on the food package. Other information about the food can be redacted if necessary to ensure confidentiality of a food product formulation.

We recognize that the composition of processed foods can vary depending on the recipe or formulation, the suppliers of ingredients, etc. For example, the amounts of given components in a mixed product, such as granola, may change if a manufacturer changes ingredient suppliers or changes a recipe. In order to verify the composition of a packaged food, the manufacturer would need to ensure that the records it provides to us to verify that the food bearing the ''healthy'' claim meets the food group equivalent requirements of § 101.65(d)(3), and, as appropriate, can distinguish among the same or similar product that the manufacturer has in the marketplace that may contain differing amounts of its components. For example, the manufacturer may have to distinguish among different granola bars with different amounts of qualifying food groups or the same granola with different formulations.

Although some manufacturers may have large numbers of foods bearing the ''healthy'' claim that would necessitate recordkeeping to verify that they meet the requirements, we do not think that determining the composition of the foods and maintaining that information would present undue difficulty for manufacturers. With or without a ''healthy'' claim, manufacturers are required to know what ingredients and nutrients are in the foods they produce and to provide that information truthfully to consumers. Manufacturers have experience with determining the ingredient composition of the food they produce and with the maintenance of related records, either written or

electronic. We seek comment on the accuracy of these assumptions.

We recognize that manufacturers frequently obtain ingredients from suppliers in a (sometimes extensive) supply chain, and that these ingredients often contain multiple ingredients themselves. Manufacturers should be able to work with their suppliers to obtain the necessary information to ensure that any food bearing the claim ''healthy'' meets the regulatory requirements to bear the claim. Ingredient suppliers should know the contents of the ingredients they provide to food manufacturers, and this information will need to be properly communicated.

We are proposing that such records must be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. We selected this period to ensure that records can be made available for review and copying as long as the product is available for purchase in the marketplace. Due to the significant number of packaged food products in the marketplace that could meet the requirements under § 101.65(d), we recognize that there could be a wide variation of manufacturing practices, shipping practices, and shelf lives among packaged foods bearing the ''healthy'' claim. We believe that it is most practical to establish a single recordkeeping period for this provision rather than establishing different recordkeeping periods for different products or for different manufacturing or shipping practices. It would be more difficult for FDA to establish a compliance program for one segment of the regulated industry that starts the recordkeeping process when the food is made, and a different compliance program for another segment of the industry that starts the recordkeeping process when the food is shipped. For manufacturers who make several food products, we expect it would be easier for them to use the same recordkeeping period for all products rather than use different recordkeeping periods for different products. Therefore, we have designed a compliance program that involves a single recordkeeping period. The proposed record requirements for purposes of verifying the ''healthy'' claim are separate and distinct from other record requirements.

We are proposing that records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610, and 81 FR 33742). The records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food meets the requirements for bearing the ''healthy'' claim. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

We anticipate that manufacturers may have concerns about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20. Thus, we are proposing to require that manufacturers must make and keep records to verify that the food meets the food group equivalent requirements of § 101.65(d)(2) where the food group equivalent contained in the product is not apparent based on the label of the food.

We are also proposing, in § 101.65(d)(4), that such records must be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. In addition, we are proposing to require that such records must be provided upon request, during an inspection, for official review and photocopying or other means of reproduction, and that records may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. All electronic records that are maintained to comply with the proposed requirements would need to comply with 21 CFR part 11.

We seek comment on the proposed requirements for the types of records that must be made and kept and the length of time that the records must be kept.

VII. Proposed Effective and Compliance Dates

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of the final rule's publication in the **Federal Register** with a compliance date 3 years after the effective date. We recognize that it may take industry time to analyze products, update their records of product labels, and print new labels. A compliance date that is 3 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner. We seek comment on the proposed compliance date.

VIII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has designated this proposed rule to be an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a large proportion of covered entities are small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Costs and Benefits

Some consumers use nutrient content claims such as ''healthy'' to inform their food purchases. We estimate that a small number (0 to 0.4 percent of people that try to follow current dietary guidelines) of these consumers would use the ''healthy'' implied nutrient content claim to make meaningful, long-lasting food purchasing decisions. If the foods using the ''healthy'' claim more closely align with Federal dietary guidance, the claim can assist consumers who are selecting those products in choosing a more healthful diet, which may result in lower chronic, diet-related diseases, including

cardiovascular disease and type 2 diabetes.

Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity stemming from consumers selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Discounted at three percent over 20 years, the mean present value of benefits accrued to consumers using the ''healthy'' nutrient content claim is $455 million, with a lower bound estimate of $15 million and an upper bound estimate of $1.3 billion. Discounted at seven percent over 20 years, the mean present value of benefits of the proposed rule is $290 million, with a lower bound estimate of $9 million and an upper bound estimate of $857 million.

Quantified costs to manufacturers associated with updating the ''healthy'' claim are labeling, reformulating, and recordkeeping. Overall, about 34,000 UPCs, or 14 percent of total UPCs, qualify for the existing ''healthy'' implied nutrient content claim but only 5 percent (12,000 UPCs) choose to label. The use of the ''healthy'' nutrient content claim is voluntary, but if the proposed rule results in some products needing to remove the claim to avoid being misbranded, manufacturers would incur costs due to the rule. Manufacturers with food products currently using the ''healthy'' nutrient content claim would need to confirm whether the products meet the proposed criteria and decide whether a label change is needed. Manufacturers with products that currently do not meet the ''healthy'' criteria but do meet the proposed criteria have the option of labeling these products. In some cases, manufacturers may choose to reformulate a product so that it meets the proposed criteria. Some recordkeeping is required for certain products using the proposed ''healthy'' claim because the required food components equivalents are likely to increase time spent on recordkeeping. It is possible that manufacturers of products that include the term ''healthy'' within the brand name may choose to rebrand products instead of reformulating. We lack the data to quantify this effect but discuss it qualitatively. Discounted at three percent over 20 years, the mean present value of costs accrued to manufacturers using the ''healthy'' nutrient content claim, assuming the current 5 percent adoption rate, is $276 million, with a lower bound of $128 million and an upper bound of $505 million. Discounted at seven percent over 20 years, the mean present value of costs of the proposed rule is $237 million, with a lower bound of $110 million and an upper bound of $434 million.

TABLE 12—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

[In millions 2020$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$27.4 30.6	$0.89 0.99	$80.9 90.4	2020 2020	7 3	20 20	Monetized benefits account for consumer's lost pleasure from eating less healthy foods they may nevertheless prefer.
Annualized Quantified					7 3		
Qualitative	To the extent consumers use the ''healthy'' nutrient content claim to maintain healthy dietary practices, following a healthy diet could reduce the risk of morbidity and prolong life.						
Costs:							
Annualized Monetized $millions/year	22.3 18.5	10.4 8.6	40.9 33.9	2020 2020	7 3	20 20	
Annualized Quantified					7 3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year.					7 3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.					7 3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government: None.							

TABLE 12—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued
[In millions 2020$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Distributional: American Indian, Alaskan Native, Hispanic, and Non-Hispanic Black adults and children, as well as the lower-income or publicly insured may accrue a larger proportion of the estimated health benefits. However, this distributional shift may be reduced if these populations do not use, or do not have access to, products that bear the ''healthy'' nutrient content claim to meaningfully change their diet. Finally, any distributional shift may be dampened if costs are passed onto consumers in the form of increased prices of foods labeled as ''healthy''. Small Business: Potential impacts on small manufacturers of packaged food and beverages due to removing the ''healthy'' claim or reformulating some products. *Wages:* None. *Growth:* None.							

We seek comment on our estimates of costs and benefits of this proposed rule.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 26) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule 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). A description of these provisions is given in the *Description* section of this document with an estimate of the annual recordkeeping and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA seeks 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.

Title: Food Labeling Regulations, OMB Control Number 0910–0381—Revision.

Description of Respondents: The respondents to this information collection are manufacturers of food products using the ''healthy'' implied nutrient content claim marketed in the United States.

Description: The proposed rule would revise § 101.65(d) to require manufacturers using the ''healthy'' implied nutrient content claim on their products to make and keep written records to verify that the products comply with this requirement. Examples of these records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. Manufacturers must provide these records upon request from FDA during an inspection for official review and photocopying or other means of reproduction.

The proposed rule would also require some manufacturers to relabel products to comply with the criteria for the ''healthy'' implied nutrient content claim. A product that does not meet the criteria would need to have the term removed from its label, and a product that became eligible would be permitted to use the term in its label.

We estimate the recordkeeping burden of this collection of information as follows:

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.65; recordkeeping to verify ''healthy'' nutrient content claim.	1,839	1	1,839	0.5 (30 minutes)	920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The proposed rule requires that each manufacturer of a food that bears the implied nutrient content claim ''healthy'' must make and keep written records to verify that the food meets the food group equivalent requirements when it is not apparent from the label of the food. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. However, the product label (including the Nutrition Facts label (NFL), the ingredient list, the statement of identity, and any other information) may be used to verify compliance with the food group requirements for certain foods. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100 percent oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetables) to bear the ''healthy'' claim. Thus, this recordkeeping estimate does not include food groups where the equivalent requirements are apparent from the label of the food. The estimates in table 13 are based on the 5,516 products estimated to need recordkeeping in table 11 of the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 26). A PRA analysis covers a 3-year period, so this number is divided by 3 to get 1,839 as an annual number of records maintained (1 record for each product). In table 13, FDA estimates that each year 1,839 manufacturers will each make and keep 1 written record for a total of 1,839 records. We estimate that each record will require 15 to 30 minutes of recordkeeping for an annual recordkeeping burden of 919.5 hours, rounded to 920 (1,839 records × 0.5 hour).

TABLE 14—ESTIMATED ONE-TIME RELABELING BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [2]
Relabel for ''healthy'' claim	5,987	1	5,987	1	5,987	$14,715,909

[1] One-time labeling burden.
[2] There are no operating and maintenance costs associated with this collection of information.

We assume there are two categories of UPCs that could require re-labeling. First, if a UPC currently labeled ''healthy'' does not meet the proposed criteria, the manufacturer could choose to remove the ''healthy'' claim or reformulate. In either case, the label would need to be changed, either to remove the ''healthy'' claim or to change the NFL after reformulation. Given the current UPCs labeled ''healthy'' that would not qualify for the proposed criteria, we estimate the number of UPCs that would remove the ''healthy'' claim or reformulate. Second, if a UPC does not currently qualify as ''healthy'' but would meet the proposed criteria, the manufacturer could choose to add the ''healthy'' claim. Table 7 of the PRIA estimates the need for 17,960 total label changes. Because this claim is voluntary, we do not know how many establishments will make labeling changes. For the purpose of this analysis, we assume that the number of respondents is the same as the number of disclosures.

We estimate that each manufacturer will relabel 1 product. A PRA analysis covers a 3-year period, so the total number of label changes, 17,960, is divided by 3 to get 5,987 annual disclosures. Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 5,987 hours. Based on table 7 of the PRIA, we estimate that there will be an annual capital cost of $14,715,909 over 3 years associated with relabeling with the total capital cost being $44,147,727. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden.

To ensure that comments on this information collection are received, OMB recommends that written comments be submitted through reginfo.gov (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides, with minor exceptions, that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to

requirements established under section 403(r) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535 (1990)); however, it is possible that such a requirement could be preempted on another basis, such as under principles of implied preemption. If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. We solicit comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, FDA proposes to amend 21 CFR part 101 as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Revise § 101.13(b)(2)(ii) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(2) * * *

(ii) Suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food (*e.g.,* healthy).

* * * * *

■ 3. Revise § 101.65(d) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) *General nutritional claims.* (1) This paragraph (d) covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food.

(2) For purposes of this section, a ''food group equivalent'' is the minimum amount of a food group that must be contained in a food for it to bear the ''healthy'' implied nutrient content claim. Food group equivalents identify the amounts of foods from each food group with qualifying nutritional content. A food group equivalent is equal to the following:

Food group	Food group equivalent	Examples
(i) Vegetable	½ cup equivalent vegetable	½ cup cooked green beans; 1 cup raw spinach.
(ii) Fruit	½ cup equivalent fruit	½ cup strawberries; ½ cup 100% orange juice; ¼ cup raisins.
(iii) Grains	No less than ¾ oz equivalent whole grain	1 slice of bread; ½ cup cooked brown rice.
(iv) Dairy	¾ cup equivalent dairy	6 oz fat free yogurt; 1⅛ oz nonfat cheese.
(v) Protein foods	1½ oz equivalent game meat	1½ oz venison.
	1 oz equivalent seafood	1 oz tuna.
	1 oz equivalent egg	1 large egg.
	1 oz equivalent beans, peas, or soy products	¼ cup black beans.
	1 oz equivalent nuts and seeds	½ oz walnuts.

(3) You may use the term ''healthy'' or related terms (*e.g.,* ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if the food meets one or more of the criteria in paragraphs (d)(3)(i) through (vi) of this section:

(i) A raw, whole fruit or vegetable.

(ii) An individual food that meets the following conditions per reference amount customarily consumed per eating occasion (RACC):

If the food is . . .	It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
(A) A vegetable product	1/2 c-eq vegetable	0% DV	10% DV	5% DV.
(B) A fruit product	1/2 c-eq fruit	0% DV	10% DV	5% DV.
(C) A grain product	¾ oz equivalent whole grain	5% DV	10% DV	5% DV.
(D) A dairy product	¾ cup equivalent dairy	5% DV	10% DV	10% DV.
(E) Protein Foods				
(*1*) Game meats	1½ oz equivalent	0% DV	10% DV	10% DV.
(*2*) Seafood	1 oz equivalent	0% DV	10% DV	10% DV.
(*3*) Egg	1 oz equivalent	0% DV	10% DV	10% DV.
(*4*) Beans, peas, and soy products	1 oz equivalent	0% DV	10% DV	5% DV.
(*5*) Nuts and seeds	1 oz equivalent	0% DV	10% DV	5% DV, excluding saturated fat derived from nuts and seeds.
(F) Oils				

If the food is . . .	It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
(*1*) 100% Oil		0% DV	0% DV	20% of total fat.
(*2*) Oil-based spreads whose fats come solely from oil.		0% DV	5% DV	20% of total fat.
(*3*) Oil-based dressing containing at least 30% oil and oils meet the requirements in paragraph (d)(3)(ii)(F)(*1*) of this section.		2% DV	5% DV	20% of total fat.

(iii) A mixed product that:

(A) Contains at least half a food group equivalent each of two different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per RACC:

If the mixed product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) ½ food group equivalent each of two of the following: fruit, vegetable, and/or protein.	0% DV	10% DV	5% DV; or 7½% DV if the protein is a game meat, seafood, or egg.
(*2*) ½ food group equivalent of whole grain and ½ food group equivalent of fruit, vegetable, or protein.	2½% DV	10% DV	5% DV; or 7½% DV if the protein is a game meat, seafood, or egg.
(*3*) ½ food group equivalent of dairy and ½ food group equivalent of fruit, vegetable, or protein.	2½% DV	10% DV	7½% DV; or 10% DV if the protein is a game meat, seafood, or egg.
(*4*) ½ food group equivalent of dairy and ½ food group equivalent of whole grain.	5% DV	10% DV	7½% DV.

(iv) A main dish product as defined in § 101.13(m) that:

(A) Contains at least one full food group equivalent each of two different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per labeled serving:

If the main dish product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) A food group equivalent each of two of the following: fruit, vegetable, and/or protein.	0% DV	20% DV	10% DV; or 15% DV if the protein is a game meat, seafood, or egg.
(*2*) A food group equivalent of whole grain and a food group equivalent of fruit, vegetable, or protein.	5% DV	20% DV	10% DV; or 15% DV if the protein is a game meat, seafood, or egg.
(*3*) A food group equivalent of dairy and a food group equivalent of fruit, vegetable, or protein.	5% DV	20% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.
(*4*) A food group equivalent of dairy and a food group equivalent of whole grain.	10% DV	20% DV	15% DV.

(v) A meal product as defined in § 101.13(l) that:

(A) Contains at least one full food group equivalent each of three different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per labeled serving:

If the meal product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) A food group equivalent each of fruits, vegetables, and protein foods.	0% DV	30% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.
(*2*) A food group equivalent of whole grain and a food group equivalent each of fruit, vegetable, and/or protein.	5% DV	30% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.

If the meal product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*3*) A food group equivalent of dairy and a food group equivalent each of fruit, vegetable, and/or protein.	5% DV	30% DV	20% DV; or 25% DV if the protein is a game meat, seafood, or egg.
(*4*) A food group equivalent of dairy, a food group equivalent of whole grain, and a food group equivalent of fruit, vegetable, and/or protein.	10% DV	30% DV	20% DV; or 25% DV if the protein is a game meat, seafood, or egg.

(vi) Plain water and plain carbonated water without any flavoring or additional ingredients.

(4) Each manufacturer of a food (other than raw, whole fruits, raw whole vegetables, water, and individual foods where the standard information required on the food label, such as the list of ingredients, provides sufficient information to verify that the food meets the food group equivalent requirements to bear the claim) that bears the implied nutrient content claim ''healthy'' must make and keep written records (*e.g.,* analyses of databases, recipes, formulations, information from recipes or formulations, or batch records) to verify that the food meets the food group equivalent requirements of paragraph (d)(2) of this section where the food group equivalent contained in the product is not apparent from the label of the food. These records must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Dated: September 22, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Geophysical Survey in the Ross Sea, Antarctica; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC218]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Geophysical Survey in the Ross Sea, Antarctica

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

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

SUMMARY: NMFS has received a request from the United States National Science Foundation (NSF) Office of Polar Programs for authorization to take marine mammals incidental to a geophysical survey in the Ross Sea, Antarctica. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than October 31, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent 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 received electronically, including all attachments, must not exceed a 25-megabyte file size. 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, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, 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 issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

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 the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

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 incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment 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 has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

On May 26, 2022, NMFS received a request from NSF for an IHA to take marine mammals incidental to conducting a low energy seismic survey and icebreaking in the Ross Sea. The application was deemed adequate and complete on July 22, 2022. NSF's request is for take of small numbers of 17 species of marine mammals by Level B harassment only. Neither NSF nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

Researchers from Louisiana State University, Texas A&M University, University of Texas at Austin, University of West Florida, and Dauphin Island Sea Lab, with funding from NSF, propose to conduct a two-part low-energy seismic survey from the Research Vessel/Icebreaker (RVIB) Nathaniel B. Palmer (NBP), in the Ross Sea during Austral Summer 2022–2023. The two-part proposed survey would include the Ross Bank and the Drygalski Trough areas. The proposed seismic survey would take place in International waters of the Southern Ocean, in water depths ranging from ~150 to 1100 meters (m).

The RVIB *Palmer* would deploy up to two 105-in^3 generator injector (GI) airguns at a depth of 1–4 m with a total maximum discharge volume for the largest, two-airgun array of 210 in^3 along predetermined track lines. During the Ross Bank survey, ~1920km of seismic data would be collected and

during the Drygalski Trough survey, ~1800 km of seismic acquisition would occur, for a total of 3720 line km.

Although the proposed survey will occur in the Austral summer, some icebreaking activities are expected to be required during the cruise.

The proposed Ross Bank portion of activity is to determine if, how, when, and why the Ross Ice Shelf unpinned from Ross Bank in the recent geologic past, to assess to what degree that event caused a re-organization of ice sheet and ice shelf flow towards its current configuration. The Drygalski Trough activities are proposed to examine the gas hydrate contribution to the Ross Sea carbon budget. The Drygalski Trough activities would examine the warming and carbon cycling of the ephemeral reservoir of carbon at the extensive bottom ocean layer-sediment interface of the Ross Sea. This large carbon reserve appears to be sealed in the form of gas hydrate and is a thermogenic carbon source and carbon storage in deep sediment hydrates. The warming and ice melting coupled with high thermogenic gas hydrate loadings suggest the Ross Sea is an essential environment to determine contributions of current day and potential future methane, petroleum, and glacial carbon to shallow sediment and water column carbon cycles.

Dates and Duration

The RVIB *Palmer* would likely depart from Lyttelton, New Zealand, on December 18, 2022, and would return to McMurdo Station, Antarctica, on January 18, 2023, after the program is completed. The cruise is expected to consist of 31 days at sea, including approximately 19 days of seismic operations (including 2 days of sea trials and/or contingency), 1 day of ocean bottom seismometer (OBS) deployment/recovery, and approximately 11 days of transit. Some deviation in timing and ports of call could also result from unforeseen events such as weather or logistical issues.

Specific Geographic Region

The proposed survey would take place in the Ross Sea, Antarctica (continental shelf between ~75°–77.7° S and 171° E–173° E and Drygalski Trough between ~74°76.7° S and 163.6° E–170° E (Figure 1) in International waters of the Southern Ocean in water depths ranging from approximately 150 to 1100 m. Representative survey tracklines are shown in Figure 1; however, the actual survey effort could occur anywhere within the outlined study area as shown. The line locations for the survey area are preliminary and could be refined in light of information from data collected during the study and conditions within the survey area.

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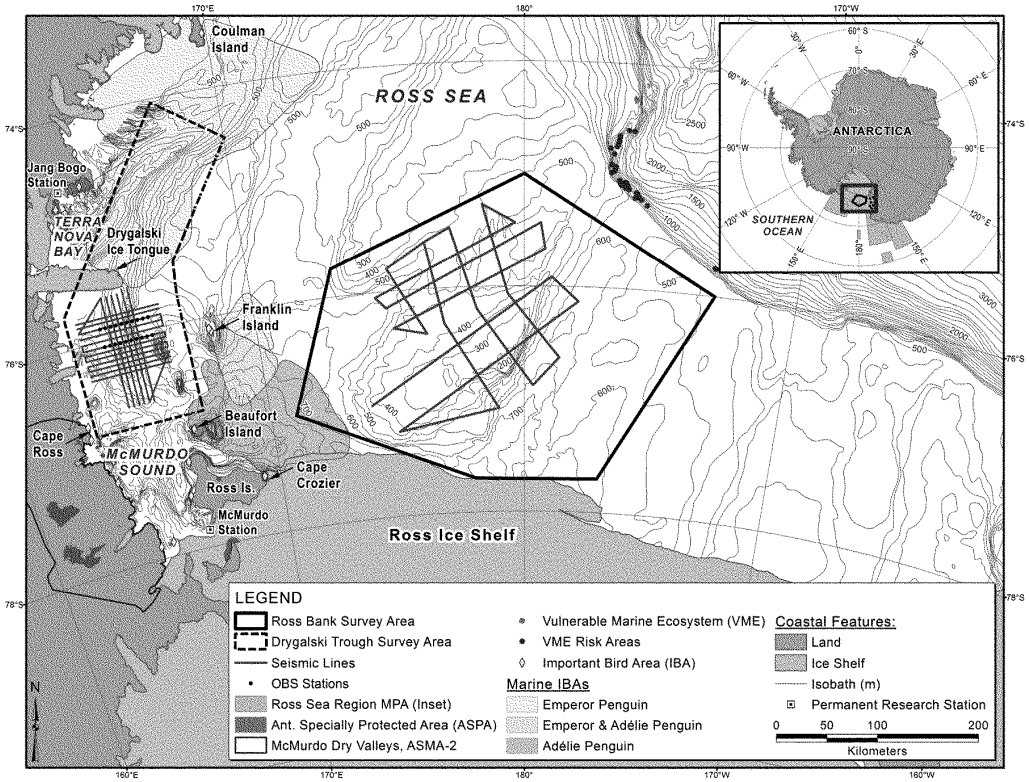

Figure 1 — Ross Sea Survey areas for the proposed low-energy seismic survey in the Ross Sea during austral summer 2022/2023*

*Showing representative transect lines and the protected areas. Ant. = Antarctic. ASMA = Antarctic Specially Managed Area. IBA = Important Bird Area. Sources: Davey (2013), CCAMLR (2017), Handley et al. (2021), and British Antarctic Survey (2022).

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Detailed Description of Specific Activity

The procedures to be used for the proposed survey would entail use of conventional seismic methodology. The survey would involve one source vessel, RVIB *Palmer* and the airgun array would be deployed at a depth of approximately 1–4 m below the surface, spaced approximately 2.4 m apart for the two-gun array. Seismic acquisition is proposed to begin with a standard sea trial to determine which configuration and mode of GI airgun(s) provide the best reflection signals, which depends on sea-state and subsurface conditions. A maximum of two GI airguns would be used. Four GI configurations (each using one or two GI airguns) would be tested during the sea trial (Table 1). The largest volume airgun configuration (configuration 4) was carried forward in our analysis and used for estimating the take numbers proposed for authorization.

The RVIB *Palmer* would deploy two 105 in^3 GI airguns as an energy source with a total volume of ~210 in^3. Seismic pulses would be emitted at intervals of 5 to 10 seconds from the GI airgun. The receiving system would consist of one hydrophone streamer, 75 m in length, with the vessel traveling at 8.3 km/hr (4.5 knots (kn)) to achieve high-quality seismic reflection data. As the airguns are towed along the survey lines, the hydrophone streamer would receive the returning acoustic signals and transfer the data to the on-board processing system. If sea-ice conditions permit, a multi-channel digital streamer would be used to improve signal-to-noise ratio by digital data processing; if ice is present, a single-channel digital steamer would be employed. When not towing seismic survey gear, the RVIB *Palmer* has a maximum speed of 26.9 km/h (14.5 kn), but cruises at an average speed of 18.7 km/h (10.1 kn). During the Ross Bank survey, ~1920km of seismic data would be collected and during the Drygalski Trough survey, ~1800 km of seismic acquisition would occur, for a total of 3720 line km.

During the Drygalski Trough survey, 2 deployments of 10 OBSs would occur along 2 different seismic refraction lines (see Fig. 1 for representative lines). Following refraction shooting of one line, OBSs on that line would be recovered, serviced, and redeployed on a subsequent refraction line. The spacing of OBSs on the initial refraction line would be 5 km apart, but OBSs could be deployed as close together as every 500 m on the subsequent refraction line. All OBSs would be recovered at the end of the survey. To retrieve the OBSs, the instrument is released via an acoustic release system to float to the surface from the wire and/or anchor, which are not retrieved.

TABLE 1—FOUR GI CONFIGURATIONS (EACH USING ONE OR TWO GI AIRGUNS) WOULD BE TESTED DURING THE SEA TRIAL

Configuration	Airgun array total volume (GI configuration)	Frequency between seismic shots	Streamer length
1	50 in^3 Harmonic Mode configured as 25 in^3 Generator + 25 Injector in^3.	5–10 seconds	75 m.
2	90 in^3 Harmonic Mode configured as 45 in^3 Generator + 45 Injector in^3.	5–10 seconds.	
3	50 in^3 True-GI Mode configured as 45 in^3 Generator + 105 Injector in^3.	5–10 seconds.	
4	210 in^3 Harmonic Mode configured as 105 in^3 Generator + 105 Injector in^3.	5–10 seconds.	

There could be additional seismic operations in the study area associated with equipment testing, re-acquisition due to reasons such as, but not limited to, equipment malfunction, data degradation during poor weather, or interruption due to shut down or track deviation in compliance with IHA requirements. To account for these additional seismic operations, 25 percent has been added in the form of operational days, which is equivalent to adding 25 percent to the proposed line km to be surveyed.

Along with the airgun and OBS operations, additional acoustical data acquisition systems and other equipment may be operated during the seismic survey at any time to meet scientific objectives. The ocean floor would be mapped with a Multibeam Ecosounder (MBES), Sub-bottom Profiler (SBP), and/or Acoustic Doppler Current Profiler (ADCP). Data acquisition in the survey area will occur in water depths ranging from 150 to 700 m. Take of marine mammals is not expected to occur incidental to use of these other sources, whether or not the airguns are operating simultaneously with the other sources. Given their characteristics (*e.g.,* narrow downward-directed beam), marine mammals would experience no more than one or two brief ping exposures, if any exposure were to occur. NMFS does not expect that the use of these sources presents any reasonable potential to cause take of marine mammals.

(1) *Single Beam Echo Sounder (Knudsen 3260)*—The hull-mounted compressed high-intensity radiated pulse (CHIRP) sonar is operated at 12 kilohertz (kHz) for bottom-tracking purposes or at 3.5 kHz in the sub-bottom profiling mode. The sonar emits energy in a 30° beam from the bottom of the ship and has a sound level of 224 dB re: 1 µPa m (rms).

(2) *Multibeam Sonar (Kongsberg EM122)*—The hull-mounted, multibeam sonar operates at a frequency of 12 kHz, has an estimated maximum source energy level of 242 dB re 1µPa (rms), and emits a very narrow (<2°) beam fore to aft and 150° in cross-track. The multibeam system emits a series of nine consecutive 15 millisecond (ms) pulses.

(3) *Acoustic Doppler Current Profiler (ADCP) (Teledyne RDI VM–150)*—The hull-mounted ADCP operates at a frequency of 150 kHz, with an estimated acoustic output level at the source of 223.6 dB re 1µPa (rms). Sound energy from the ADCP is emitted as a 30°, conically shaped beam.

(4) *ADCP (Ocean Surveyor OS–38)*—The characteristics of this backup, hull-mounted ADCP unit are similar to the Teledyne VM–150. The ADCP operates at a frequency of 150 kHz with an estimated acoustic output level at the source of 223.6 dB re 1µPa (rms). Sound energy from the ADCP is emitted as a 30° conically-shaped beam.

(5) *EK biological echo sounder (Simrad ES200–7C, ES38B, ES–120–7C)*—This echo sounder is a split-beam transducer with an estimated acoustic output level at the source of 183–185 dB

re 1μPa and emits a 7° beam. It can operate at 38 kHz, 120 kHz and 200 kHz.

(6) *Acoustic Release*—To retrieve OBSs, an acoustic release transponder (pinger) is used to interrogate the instrument at a frequency of 8–11 kHz, and a response is received at a frequency of 7–15 kHz. The burn-wire release assembly is then activated, and the instrument is released to float to the surface from the wire and/or anchor which are not retrieved.

(7) *Oceanographic Sampling*—during the Drygalski Trough study, the researchers would also conduct opportunistic oceanographic sampling as time and scheduling allows, including conductivity, temperature and depth (CTD) measurements, box cores, and/or multi-cores.

Icebreaking

Icebreaking activities are expected to be limited during the proposed survey. The Ross Sea is generally clear of ice January through February, because of the large Ross Sea Polynya that occurs in front of the Ross Ice Shelf. Heavy ice conditions would hamper the proposed activities, as noise from icebreaking degrades the quality of the geophysical data to be acquired. If the RVIB *Palmer* would find itself in heavy ice conditions, it is unlikely that the airgun(s) and streamer could be towed, as this could damage the equipment and generate noise interference. The seismic survey could take place in low ice conditions if the RVIB *Palmer* were able to generate an open path behind the vessel. The RVIB *Palmer* is not rated for breaking multi-year ice and generally avoids transiting through ice two years or older and more than 1 m thick. If sea ice were to be encountered during the survey, the RVIB *Palmer* would likely proceed through one-year sea ice, and new, thin ice, but would follow leads wherever possible. Any time spent icebreaking would take away time from the proposed research activities, as the vessel would travel slower in ice-covered seas. Based on estimated transit to the survey area, it is estimated that the RVIB *Palmer* would break ice up to a distance of 500 km. Based on a ship speed of 5 kn under moderate ice conditions, this distance represents approximately 54 hours of icebreaking (or 2.2 days). Transit through areas of primarily open water containing brash ice or pancake ice is not considered icebreaking for the purposes of this assessment.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

The populations of marine mammals considered in this document do not occur within the U.S. Exclusive Economic Zone (EEZ) and are therefore not assigned to stocks and are not assessed in NMFS' Stock Assessment Reports (SAR). As such, information on potential biological removal (PBR; defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population) and on annual levels of serious injury and mortality from anthropogenic sources are not available for these marine mammal populations. Abundance estimates for marine mammals in the survey location are lacking; therefore estimates of abundance presented here are based on a variety of other sources including International Whaling Commission (IWC) population estimates, the International Union for Conservation of Nature's (IUCN) Red List of Threatened Species, and various literature estimates (see IHA application for further detail), as this is considered the best available information on potential abundance of marine mammals in the area.

Seventeen species of marine mammals could occur in the Ross Sea, including 5 mysticetes (baleen whales), 7 odontocetes (toothed whales) and 5 pinniped species (Table 2). Another seven species occur in the Sub-Antarctic but are unlikely to be encountered in the proposed survey areas, as they generally occur farther to the north than the project area. These species are not discussed further here but include: the southern right whale (*Eubalaena australis*), common (dwarf) minke whale (*Balaenoptera acutorostrata*), Cuvier's beaked (*Ziphius cavirostris*), Gray's beaked (*Mesoplodon grayi*), Hector's beaked (*Mesoplodon hectori*), and spade-toothed beaked (*Mesoplodon traversii*) whales, southern right whale dolphin (*Lissodelphis peronii*), and spectacled porpoise (*Phocoena dioptrica*). Table 2 lists all species with expected potential for occurrence in the Ross Sea, Antarctica, and summarizes information related to the population, including regulatory status under the MMPA and ESA.

TABLE 2—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN THE PROJECT AREA EXPECTED TO BE AFFECTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock[1]	ESA/ MMPA status; strategic (Y/N)[2]	Stock abundance
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)				
Family Balaenopteridae (rorquals):				
Blue whale	*Balaenoptera musculus*	N/A	E/D;Y	10,000–25,000.[5] 1,700.[7]
Fin whale	*Balaenoptera physalus*	N/A	E/D;Y	140,000.[5] 38,200. [6]
Humpback whale	*Megaptera novaeangliae*	N/A		90,000.–100,000.[5] 80,000.[10] 42,000.[11]
Antarctic minke whale[6]	*Balaenoptera bonaerensis*	N/A		Several 100,000 [5] 515,000.[9]

TABLE 2—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN THE PROJECT AREA EXPECTED TO BE AFFECTED BY THE SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock[1]	ESA/ MMPA status; strategic (Y/N)[2]	Stock abundance
Sei whale	*Balaenoptera borealis*	N/A	E	70,000.[8]
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)				
Family Physeteridae:				
Sperm whale	*Physeter macrocephalus*	N/A	E	360,000.[12] 12,069.[13]
Family Ziphiidae (beaked whales):				
Arnoux's beaked whale	*Berardius arnuxii*	N/A		599,300.[14]
Strap-toothed beaked whale	*Mesoplodon grayi*	N/A		599,300.[14]
Southern bottlenose whale	*Hyperoodon planifrons*	N/A		599,300.[14]
Family Delphinidae:				
Killer whale	*Orcinus orca*	N/A		50,000 [16] 25,000.[17]
Long-finned pilot whale	*Globicephala macrorhynchus*	N/A		200,000.[15]
Hourglass dolphin	*Lagenorhynchus cruciger*	NA		144,300.[15]
Family Phocidae (earless seals):				
Crabeater seal	*Lobodon carcinophaga*	N/A		5–10 million [18] 1.7 million.[19]
Leopard seal	*Hydrurga leptonyx*	N/A		222,000–440,00.[5 20]
Southern elephant seal	*Mirounga leonina*	N/A		750,000.[23]
Ross seal	*Ommatophoca rossii*	N/A		250,000.[22]
Weddell seal	*Leptonychotes weddellii*	N/A		1 million.[5 21]

N.A. = data not available.
[1] Occurrence in area at the time of the proposed activities; based on professional opinion and available data.
[2] U.S. Endangered Species Act: EN = endangered, NL = not listed.
[5] Worldwide (Jefferson *et al.,* 2015).
[6] Antarctic (Aguilar and García-Vernet 2018).
[7] Antarctic (Branch *et al.,* 2007).
[8] Southern Hemisphere (Horwood 2018).
[9] Southern Hemisphere (IWC 2020).
[10] Southern Hemisphere (Clapham 2018).
[11] Antarctic feeding area (IWC 2020).
[12] Worldwide (Whitehead 2002).
[13] Antarctic south of 60° S (Whitehead 2002).
[14] All beaked whales south of the Antarctic Convergence; mostly southern bottlenose whales (Kasamatsu and Joyce 1995).
[15] Kasamatsu and Joyce (1995).
[16] Worldwide (Forney and Wade 2006).
[17] Minimum estimate for Southern Ocean (Branch and Butterworth 2001).
[18] Worldwide (Bengtson and Stewart 2018).
[19] Ross and Amundsen seas (Bengtson *et al.,* 2011).
[20] Rogers *et al.,* 2018.
[21] Hückstädt 2018a.
[22] Worldwide (Curtis *et al.,* 2011 in Hückstädt 2018b).
[23] Total world population (Hindell *et al.,* 2016).

All species that could potentially occur in the proposed survey areas are included in Table 2. As described below, all 17 species temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it.

We have reviewed NSF's species descriptions, including life history information, distribution, regional distribution, diving behavior, and acoustics and hearing, for accuracy and completeness. We refer the reader to Section 4 of NSF's IHA application for a complete description of the species, and offer a brief introduction to the species here, as well as information regarding population trends and threats, and describe information regarding local occurrence.

Mysticetes

Blue Whale

The blue whale has a cosmopolitan distribution, but tends to be mostly pelagic, only occurring nearshore to feed and possibly breed (Jefferson *et al.,* 2015). It is most often found in cool, productive waters where upwelling occurs (Reilly and Thayer 1990). The distribution of the species, at least during times of the year when feeding is a major activity, occurs in areas that provide large seasonal concentrations of euphausiids (Yochem and Leatherwood 1985). Seamounts and other deep ocean structures may be important habitat for blue whales (Lesage *et al.,* 2016).

Generally, blue whales are seasonal migrants between high latitudes in summer, where they feed, and low latitudes in winter, where they mate and give birth (Lockyer and Brown 1981).

Historically, blue whales were most abundant in the Southern Ocean. Although, the population structure of the Antarctic blue whale (*Balaenoptera musculus intermedia*) in the Southern Ocean is not well understood, there is evidence of discrete feeding stocks (Sears & Perrin 2018). Cooke (2018) explains that ''there are no complete estimates of recent or current abundance for the other regions, but plausible total numbers would be 1,000–3,000 in the North Atlantic, 3,000–5,000 in the North Pacific, and possibly 1,000–3,000 in the eastern South Pacific. The number of Pygmy Blue whales is very uncertain but may be in the range 2,000–5,000. Taken together with a range of 5,000–8,000 in the Antarctic, the global population size in 2018 is plausibly in the range 10,000–25,000 total or 5,000–15,000 mature, compared with a 1926 global population of at least 140,000 mature.'' Blue whales begin migrating north out of the Antarctic to winter breeding grounds earlier than fin and sei whales.

The Antarctic blue whale is typically found south of 55° S during summer, although some individuals do not migrate (Branch *et al.,* 2007a). The blue whale is considered to be rare in the Southern Ocean; up to 360,000 blue whales were harvested in the Southern Hemisphere in the early 20th century (Sears and Perrin 2018). Ainley (2010) noted that they were extirpated from the Ross Sea shelf break front in the 1920s. Smith *et al.* (2012) estimated that 30 blue whales may occur in the Ross Sea. Several sighting records were reported for the northern Ross Sea between 1978 and 2005 (Kasamatsu *et al.,* 1990; Nishiwaki *et al.,* 1997; Matsuoka *et al.,* 2006; Ainley *et al.,* 2010) as well as during a 2008 survey (Baird and Mormede 2014). Acoustic detections were also made in the northeastern Ross Sea between 1996 to 2010 (Shabangu *et al.,* 2018). Eight groups of 24 individuals were seen north of the Ross Sea during summer surveys in 2002–2003 (Ensor *et al.,* 2003). No blue whales were seen during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a).

Fin Whale

The fin whale is widely distributed in all the world's oceans (Gambell 1985), although it is most abundant in temperate and cold waters (Aguilar and García-Vernet 2018). Nonetheless, its overall range and distribution is not well known (Jefferson *et al.,* 2015). Fin whales most commonly occur offshore, but can also be found in coastal areas (Jefferson *et al.,* 2015). Most populations migrate seasonally between temperate waters where mating and calving occur in winter, and polar waters where feeding occurs in the summer; they are known to use the shelf edge as a migration route (Evans 1987). The northern and southern fin whale populations likely do not interact owing to their alternate seasonal migration; the resulting genetic isolation has led to the recognition of two subspecies, *B. physalus quoyi* and *B. p. physalus* in the Southern and Northern hemispheres, respectively (Anguilar and García-Vernet 2018).

They likely migrate beyond 60° S during the early to mid-austral summer, arriving at southern feeding grounds after blue whales. Overall, fin whale density tends to be higher outside the continental slope than inside it. During the austral summer, the distribution of fin whales ranges from 40° S–60° S in the southern Indian and South Atlantic oceans and 50° S–65° S in the South Pacific. Aguilar and García-Vernet (2018) found abundance estimates resulted in 38,200 individuals in the Antarctic south of 307° S.

Based on Edwards *et al.* (2015), densities in the Southern Ocean south of 60° S (including the northern part of the Ross Sea) are highest during December–February, with non-zero densities <0.003 whales/km^2. Pinkerton *et al.* (2010) assumed that ~200 fin whales use the Ross Sea during summer. Fin whale sightings have been reported for the Ross Sea by several authors (Nishiwaki *et al.,* 1997; Matsuoka *et al.,* 2006; Ainley *et al.,* 2010; Baird and Mormede 2014; MacDiarmid and Stewart 2015). During an NSF-funded seismic survey in the Ross Sea in January through February 2015, 13 sightings totaling 34 fin whales were made, including within the proposed survey area (RPS 2015a). Ensor *et al.* (2003) reported sightings north of the Ross Sea during summer surveys in 2002–2003.

Humpback Whale

The humpback whale is found in all ocean basins (Clapham 2018). Based on genetic data, there could be three subspecies, occurring in the North Pacific, North Atlantic, and Southern Hemisphere (Jackson *et al.,* 2014). The humpback whale is highly migratory, undertaking one of the world's longest mammalian migrations by traveling between mid- to high-latitude waters where it feeds during spring to fall and low-latitude wintering grounds over shallow banks, where it mates and calves (Winn and Reichley 1985; Bettridge *et al.,* 2015). Although considered to be mainly a coastal species, it often traverses deep pelagic areas while migrating (Baker *et al.,* 1998; Garrigue *et al.,* 2002; Zerbini *et al.,* 2011).

In the Southern Hemisphere, humpback whales migrate annually from summer foraging areas in the Antarctic to breeding grounds in tropical seas (Clapham 2018). The IWC recognizes seven breeding populations in the Southern Hemisphere that are linked to six foraging areas in the Antarctic (Bettridge *et al.,* 2015; Clapham 2018). Humpbacks that occur in the western Ross Sea (west of 170° W) are part of the Area V feeding stock (Schmitt *et al.,* 2014); these individuals are from the Oceania DPS that breeds in French Polynesia, Cook Islands, and Tonga, and from the East Australia DPS (Schmitt *et al.,* 2014; Bettridge *et al.,* 2015).

Humpback densities are high north of the Ross Sea (Branch 2011; Matsuoka and Hakamada 2020), but not within it (Ropert-Coudert *et al.,* 2014). Pinkerton *et al.* (2010) estimated that <5 percent (150 individuals) of the Southern Ocean population occurs in the Ross Sea in the austral summer. Humpback whales were seen in the northern Ross Sea during surveys conducted between 1987 and 2009 (Baird and Mormede 2014; MacDiarmid and Stewart 2015). However, none were seen in the Ross Sea during the International Whaling Commission-Southern Ocean Whale and Ecosystem Research (IDCR/SOWER) surveys from 1978/79 to 2004/05 (Branch 2011). During an NSF-funded seismic survey in the Ross Sea in January–February 2015, two sightings totaling six individuals were made east of the proposed survey areas (RPS 2015a). Acoustic detections were also made in the northeastern Ross Sea between 1996 to 2010 (Shabangu *et al.,* 2018). Ensor *et al.* (2003) reported numerous humpback sightings and acoustic detections north of the Ross Sea during summer surveys in 2002–2003.

Antarctic Minke Whale

The Antarctic minke whale has a circumpolar distribution in coastal and offshore areas of the Southern Hemisphere from ~7 degrees S to the ice edge (Jefferson *et al.,* 2015). It is found between 60° S and the ice edge during the austral summer; in the austral winter, it is mainly found at mid-latitude breeding grounds, including off western South Africa and northeastern Brazil, where it is primarily oceanic,

occurring beyond the shelf break (Perrin *et al.,* 2018). Antarctic minke whale densities are highest near pack ice edges, although they are also found amongst pack ice (Ainley *et al.,* 2012; Williams *et al.,* 2014), where they feed almost entirely on krill (Tamura and Konishi 2009). Murase *et al.* (2006, 2007) found that minke whale distribution was related to krill density in the Ross Sea, with the greatest number of pods in areas with a krill density of 1 g/m^2.

Minke whales were harvested heavily in the Southern Ocean during the 1970s and 1980s, with >13,000 harvested in the early 1980s; but the hunt ceased in 1986 under an IWC moratorium (Ainley 2002). However, Japanese whaling continued under scientific permit taking hundreds of minke whales in the Ross Sea since the late 1980s (Ainley 2002). During Japanese sighting surveys from 1976–1988, high encounter rates occurred in the Ross Sea (Kasamatsu *et al.,* 1996), where minke whales are known to form feeding aggregations (Kasamatsu *et al.,* 1998). Saino and Guglielmo (2002) reported a mean density of 0.13 whales/km^2 in the western Ross Sea. The minke whale is the most abundant species occupying the shelf waters in the Ross Sea (Waterhouse 2001; Smith *et al.,* 2007). Approximately six percent of Antarctic minke whales occur in the Ross Sea (Ainley *et a,l.* 2010; Smith *et al.,* 2012). The Ross Sea population was estimated at 14,300 by Ainley (2002) and 87,643 individuals by Matsuoka *et al.,* (2009).

Ainley *et al.* (2017) reported that minke whales started to arrive in the southwestern Ross Sea in mid-November, with decreasing ice conditions. Ainley *et al.* (2010, 2012) and Ballard *et al.* (2012) reported sightings around the northwestern and northeastern periphery of the proposed Ross Bank survey area and within the Drygalski Trough survey area. Although minke whales have a high likelihood of occurrence in the Ross Sea (*e.g.,* Ainley *et al.,* 2012; Ropert-Coudert *et al.,* 2014), habitat suitability for the proposed survey area in summer was modeled as relatively low (Ballard *et al.,* 2012). However, minke whales were seen in the Ross Sea during surveys conducted between 1978 and 2009, including within the proposed survey area (Kasamatsu *et al.,* 1990; Baird and Mormede 2014; MacDiarmid and Stewart 2015). They were also detected acoustically in the Ross Sea in 2004 (Dolman *et al.,* 2005). Minke whales were seen feeding (presumable on fish) in the southwestern Ross Sea (Lauriano *et al.,* 2007). During an NSF-funded seismic survey in the Ross Sea in January–February 2015, 224 sightings totaling 1023 minke whales were made, including within the proposed survey area and in McMurdo Sound (RPS 2015a). Ensor *et al.* (2003) reported numerous sightings north of the Ross Sea during summer surveys in 2002–2003.

Sei Whale

The sei whale occurs in all ocean basins (Horwood 2018), predominantly inhabiting deep waters throughout their range (Acevedo *et al.,* 2017a). It undertakes seasonal migrations to feed in sub-polar latitudes during summer, returning to lower latitudes during winter to calve (Horwood 2018). Recent observation records indicate that the sei whale may utilize the Vitória-Trindade Chain off Brazil as calving grounds (Heissler *et al.,* 2016). In the Southern Hemisphere, sei whales typically concentrate between the Subtropical and Antarctic convergences during the summer (Horwood 2018) between 40° S and 50° S, with larger, older whales typically travelling into the northern Antarctic zone while smaller, younger individuals remain in the lower latitudes (Acevedo *et al.,* 2017a). Pinkerton *et al.* (2010) assumed that approximately 100 animals may occur in the Ross Sea. Ensor *et al.* (2003) reported no sightings south of 54° S during a summer survey of the Southern Ocean in 2002–2003. No sei whales were seen during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a).

Odontocetes

Sperm Whale

The sperm whale is widely distributed, occurring from the edge of the polar pack ice to the Equator in both hemispheres, with the sexes occupying different distributions (Whitehead 2018). In general, it is distributed over large temperate and tropical areas that have high secondary productivity and steep underwater topography, such as volcanic islands (Jaquet and Whitehead 1996). Its distribution and relative abundance can vary in response to prey availability, most notably squid (Jaquet and Gendron 2002). Females generally inhabit waters greater than 1,000 m deep at latitudes less than 40° where sea surface temperatures are less than 15 °C; adult males move to higher latitudes as they grow older and larger in size, returning to warm-water breeding grounds according to an unknown schedule (Whitehead 2018).

Few sperm whales are thought to occur in the Ross Sea (Smith *et al.,* 2012), although Pinkerton *et al.* (2010) assumed that 800 sperm whales could be using the Ross Sea. Sperm whales generally do not occur south of approximately 73–74° S in the Ross Sea (Matsuoka *et al.,* 1998; Ropert-Coudert *et al.,* 2014). Nonetheless, sperm whales have been reported there by several authors (Kasamatsu *et al.,* 1990; Baird and Mormede 2014). Ensor *et al.* (2003) reported numerous sightings and acoustic detections north of the Ross Sea during summer surveys in 2002–2003. No sperm whales were seen during an NSF-funded seismic survey in the Ross Sea in January through February 2015 (RPS 2015a).

Arnoux's Beaked Whale

Arnoux's beaked whale is distributed in deep, cold, temperate, and subpolar waters of the Southern Hemisphere, occurring between 24° S and Antarctica (Thewissen 2018), as far south as the Ross Sea at approximately 78° S (Perrin *et al,.* 2009). Most records exist for southeastern South America, Falkland Islands, Antarctic Peninsula, South Africa, New Zealand, and southern Australia (MacLeod *et al.,* 2006; Jefferson *et al.,* 2015).

Ainley *et al.* (2010) and Van Waerebeek *et al.* (2010), and Ropert-Coudert *et al.* (2014) reported their occurrence in the Ross Sea. Lauriano *et al.* (2011) reported two sightings of single individuals in Terra Nova Bay, western Ross Sea, during summer 2004 surveys. There may be 50 (Pinkerton *et al.,* 2010) to 150 (Smith *et al.,* 2012) Arnoux's beaked whales in the Ross Sea. No Arnoux's beaked whales were seen during an NSF-funded seismic survey in the Ross Sea in January through February 2015 (RPS 2015a).

Southern Bottlenose Whale

The southern bottlenose whale is found throughout the Southern Hemisphere from 30° S to the ice edge, with most sightings reported between approximately 57° S and 70° S (Jefferson *et al.,* 2015; Moors-Murphy 2018). Several sighting and stranding records exist for southeastern South America, Falkland Islands, South Georgia Island, southeastern Brazil, Argentina, South Africa, and numerous sightings have been reported for the Southern Ocean (Findlay *et al.,* 1992; MacLeod *et al.* 2006; Riccialdelli *et al.,* 2017). The population size of southern bottlenose whales in the Ross Sea was assumed to be 500 by Pinkerton *et al.* (2010). Ropert-Coudert *et al.* (2014) reported their occurrence in the Ross Sea, and Kasamatsu *et al.* (1990) reported sightings between 1978 and 1988. Southern bottlenose whales were also sighted in the northern Ross Sea and

north of there during surveys of the Southern Ocean by Van Waerebeek *et al.* (2010). Several unidentified beaked whales have also been reported in the Ross Sea, including in the Ross Bank survey area and near the Drygalski Trough survey area (Baird and Mormede 2014; MacDiarmid and Stewart 2015; Matsuoka and Hakamada 2020). Ensor *et al.* (2003) and Matsuoka and Hakamada (2020) reported numerous sightings of southern bottlenose whales north of the Ross Sea. No bottlenose whales were seen during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a).

Strap-Toothed Beaked Whale

The strap-toothed beaked whale is thought to have a circumpolar distribution in temperate and subantarctic waters of the Southern Hemisphere, mostly between 32° and 63° S (MacLeod *et al.,* 2006; Jefferson *et al.,* 2015). It is likely quite common in the Southern Ocean (Pitman 2018). It may undertake limited migration to warmer waters during the austral winter (Pitman 2018). Strap-toothed beaked whales are thought to migrate northward from Antarctic and subantarctic latitudes during April–September (Sekiguchi *et al,.* 1995). One group of three strap-toothed beaked whales was seen north of the Ross Sea, north of 65° S, during a 2002 through 2003 summer survey (Ensor *et al.,* 2003). No strap-toothed beaked whales were seen during an NSF-funded seismic survey in the Ross Sea in January through February 2015 (RPS 2015a).

Killer Whale

The killer whale is cosmopolitan and globally abundant; it has been observed in all oceans of the world (Ford 2018). It is very common in temperate waters but also occurs in tropical waters (Heyning and Dahlheim 1988) and inhabits coastal and offshore regions (Budylenko 1981). Mikhalev *et al.* (1981) noted that it appears to migrate from warmer waters during the winter to higher latitudes during the summer. In the Antarctic, it commonly occurs up to the pack ice edge but may also find its way into ice-covered water (Ford 2018).

There are three ecotypes that occur in Antarctic waters: type A hunts marine mammals in open water, mainly seeking minke whales, type B hunt seals in loose pack ice, and type C feeds on fish in dense pack ice (Pitman and Ensor 2003); these types are likely different species (Morin *et al.,* 2010; Pitman *et al.,* 2017). Type D occurs in subantarctic waters and is also likely a separate species (Pitman *et al.,* 2011). Type B travels widely to hunt its prey, whereas type C is more resident (Andrews *et al.,* 2008). In fact, type Cs (Ross Sea killer whales) appear to have resident and transient groups in the Ross Sea (*e.g.,* Ainley *et al.,* 2017). In the Ross Sea, abundance has been estimated at 7500 individuals (Smith *et al.,* 2007). Ainley *et al.* (2010) and Smith *et al.* (2012) estimated that approximately 50 percent of Ross Sea killer whales use the Ross Sea during summer foraging. Smith *et al.* (2012) reported 3350 type C killer whales and 70 type A/B killer whales in the Ross Sea. Pitman *et al.* (2017) reported only two ecotypes in the Ross Sea (types B and C), but Ainley *et al.* (2010) noted that type A could occur along the slope.

Ainley *et al.* (2017) reported that type C and B killer whales start to arrive in the southwestern Ross Sea in mid-November, with decreasing ice conditions, with type Bs arriving earlier than type Cs. Type C killer whales have been seen feeding (presumable on fish) in the southwestern Ross Sea (Lauriano *et al.,* 2007), and type B and C killer whales were reported during summer 2004 surveys in Terra Nova Bay, western Ross Sea (Lauriano *et al.,* 2011). Eisert *et al.* (2014) reported Type C and B in McMurdo Sound. Type C killer whales have also been detected acoustically in McMurdo Sound (Wellard *et al.,* 2020). During an NSF-funded seismic survey in the Ross Sea in January through February 2015, 14 sightings totaling 254 killer whales were made, including within the survey area and in McMurdo Sound (RPS 2015a). Saino and Guglielmo (2002) reported a mean density of 0.05 whales/km^2 in the western Ross Sea. However, numbers of type C killer whales have apparently decreased in the southwestern Ross Sea, because of changes in prey distribution (Antarctic toothfish) likely brought on by fishing pressures (Ainley *et al.,* 2009; Ainley and Ballard 2012). However, Pitman *et al.* (2018) suggested that the presence of a mega-iceberg at Ross Island may have also impeded killer whale movement, thereby affecting the population size; they estimated a population size of 470 distinct individuals in McMurdo Sound. Type B killer whale numbers have not changed in the southern Ross Sea, where they hunt Weddell seals and emperor penguins (Ainley and Ballard 2012).

Type C killer whale appears to favor the Ross Sea shelf and slope (Ballard *et al.,* 2012). Sightings of type C killer whales within and west of the proposed study area have been reported during summer (Andrews *et al.,* 2008; Ballard *et al.,* 2012). The habitat suitability for the proposed survey area in summer for type C killer whales was modeled as relatively high, whereas it was lower for the Drygalski Trough survey area (Ballard *et al.,* 2012). Andrew *et al.* (2008) documented movement of a tagged type B killer whale to the west of the proposed study area. Aubrey *et al.* (1982) reported sightings of killer whales in the Ross Sea off Cape Adare and over Pennell Banks, and noted that killer whales were abundant off Ross Island. Killer whales were also reported in the Ross Sea by several other authors (*e.g.,* Kasamatsu *et al.,* 1990; Van Dam and Kooyman 2004; Van Waerebeek *et al.,* 2010; Baird and Mormede 2014; Ropert-Coudert *et al.,* 2014). Acoustic detections were also made in the northeastern Ross Sea between 1996 to 2010 (Shabangu *et al.,* 2018). Ensor *et al.* (2003) reported numerous sightings and acoustic detections north of the Ross Sea during summer surveys in 2002–2003.

Long-Finned Pilot Whales

The long-finned pilot whale is distributed antitropically in cold temperate waters, including the Southern Ocean, whereas the short-finned pilot whale is found in tropical and warm temperate waters (Olson 2018). The ranges of the two species show little overlap (Olson 2018). Long-finned pilot whales are geographically isolated and separated into two subspecies, *G. melas melas* and *G. melas edwardii* in the Northern and Southern hemispheres, respectively (Olson 2018). In the Southern Hemisphere, their range extends to the Antarctic Convergence and sometimes as far south as 68° S (Jefferson *et al.,* 2015). Although generally not seen south of 68° S, long-finned pilot whales were reported in the Ross Sea during observations from longliners between 1997 and 2009 (Baird and Mormede 2014). During summer surveys in 2002–2003, several sightings were made north of the Ross Sea (Ensor *et al.,* 2003). They were also reported north of the Ross Sea during surveys by Van Waerebeek *et al.* (2010). No pilot whales were seen during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a).

Hourglass Dolphin

The hourglass dolphin occurs in the Southern Ocean, with most sightings between approximately 45° S and 60° S (Cipriano 2018). However, some sightings have been made as far north as 33° S (Jefferson *et al.,* 2015). Hourglass dolphins were sighted near 45° S, north of the Ross Sea, during surveys of the Southern Ocean (Van Waerebeek *et al.,*

2010). Although it is pelagic, it is also sighted near banks and islands (Cipriano 2018). Ensor *et al.* (2003) reported numerous sightings of hourglass dolphins north of the Ross Sea, north of 65° S, during a summer survey in 2002–2003. No hourglass dolphins were seen during an NSF-funded seismic survey in the Ross Sea in January through February 2015 (RPS 2015a).

Phocids

Crabeater Seal

The crabeater seal has a circumpolar distribution off Antarctica and is the most abundant seal in the region, sometimes congregating in the hundreds (Bengtson and Stewart 2018). It generally spends the entire year in the advancing and retreating pack ice (Bengtson and Stewart 2018). However, outside of the breeding season, crabeater seals spend ~14 percent of their time in open water (reviewed in Southwell *et al.,* 2012); they mainly forage on krill. During the breeding season, crabeater seals are most likely to be present within 5° or less (~550 km) of the shelf break; non-breeding animals range farther north (Southwell *et al.,* 2012). Pupping season peaks in mid- to late-October, and adults are observed with their pups as late as mid-December (Bengtson and Stewart 2018).

Crabeater seals are most common in the pack ice of the northern Ross Sea (Waterhouse 2001). A population of approximately 204,000 has been estimated for the Ross Sea (Waterhouse 2001; Ainley 2002, 2010; Pinkerton and Bradford-Grieve 2010; Smith *et al.,* 2012). Crabeater seals have been reported for the Ross Sea by several authors (Stirling 1969; Van Dam and Kooyman 2004; Bester and Stewart 2006; Baird and Mormede 2014; Ropert-Coudert *et al.,* 2014). Crabeater seals have been sighted within the proposed survey area (*e.g.,* Saino and Guglielmo 2000; Ainley *et al.,* 2010; Ballard *et al.,* 2012), with greater habitat suitability in summer in the Drygalski Trough survey area than in the Ross Bank survey area (Ballard *et al.,* 2012). Similarly, Bengtson *et al.* (2011) reported relatively low densities in the Ross Bank area and higher densities in the Drygalski Trough area. Saino and Guglielmo (2002) showed increasing densities with increasing pack ice and distance from shore, with a mean density of 0.49 seals/km^2, in the western Ross Sea. In contrast, Bengtson *et al.* (2011) reported the highest density (1.3 seals/km^2) on the shelf at distances up to 200 km from the ice edge during surveys of the Ross and Amundsen seas; densities in the proposed survey area were estimated to be low. During an NSF-funded seismic survey in the Ross Sea in January through February 2015, 9 sightings of 14 individuals were made (RPS 2015a).

Leopard Seal

The leopard seal has a circumpolar distribution around the Antarctic continent where it is solitary and widely dispersed at low densities (Rogers 2018). It primarily occurs in pack ice, but when the sea ice extent is reduced, it can be found in coastal habitats (Meade *et al.,* 2015). Leopard seals are top predators, consuming everything from krill and fish to penguins and other seals (*e.g.,* Hall-Aspland and Rogers 2004). Pups are born during October to mid-November and weaned ~one month later (Rogers 2018). Mating occurs in the water during December and January. A population of ~8000 is thought to occur in the Ross Sea (Waterhouse 2001; Ainley 2002, 2010; Pinkerton and Bradford-Grieve 2010; Smith *et al.,* 2012). Bengtson *et al.* (2011) reported an abundance of 15,000 leopard seals for the Ross and Amundsen seas. Densities were highest (0.024 seals/km^2) in water <3000 m deep and <100 km from the ice edge; very low densities were estimated for the southern portion of the Ross Bank survey area, with low densities in the rest of the survey area and in the Drygalski Trough survey area (Bengtson *et al.,* 2011). Leopard seals have been documented to take Adélie penguins at several colonies in the Ross Sea, including Cape Crozier (south of the proposed survey areas), and in McMurdo Sound (Ainley *et al.,* 2005). Leopard seals have been reported within and near the Drygalski Trough survey area, no sightings have been reported within the Ross Bank survey area (Stirling 1969; Ackley *et al.,* 2003; Van Dam and Kooyman 2004; Bester and Stewart 2006; Ainley *et al.,* 2010; Baird and Mormede 2014; Ropert-Coudert *et al.,* 2014). No leopard seals were sighted during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a).

Southern Elephant Seal

The southern elephant seal has a near circumpolar distribution in the Southern Hemisphere (Jefferson *et al.,* 2015), with breeding sites located on islands throughout the subantarctic (Hindell 2018). Breeding colonies are generally island-based, with the occasional exception of the Antarctic mainland (Hindell 2018).

When not breeding (September–October) or molting (November–April), southern elephant seals range throughout the Southern Ocean from areas north of the Antarctic Polar Front to the pack ice of the Antarctic, spending >80 percent of their time at sea each year, up to 90 percent of which is spent submerged while hunting, travelling, and resting in water depths ≥200 m (Hindell 2018). Males generally feed in continental shelf waters, while females preferentially feed in ice-free Antarctic Polar Front waters or the marginal ice zone in accordance with winter ice expansion (Hindell 2018). Southern elephant seals tagged at South Georgia showed long-range movements from ~April through October into the open Southern Ocean and to the shelf of the Antarctic Peninsula (McConnell and Fedak 1996). Their occurrence in the Ross Sea is rare and only during the summer (Waterhouse 2001; Pinkerton and Bradford-Grieve 2010). The population size in the Ross Sea is estimated to number <100 individuals (Ainley 2010; Smith *et al.,* 2012). Ropert-Coudert *et al.* (2014) reported one record in the Ross Sea, in McMurdo Sound. No southern elephant seals were seen during an NSF-funded seismic survey in the Ross Sea in January–February 2015 (RPS 2015a)

Ross Seal

Ross seals are considered the rarest of all Antarctic seals; they are the least documented because they are infrequently observed. Ross seals have a circumpolar Antarctic distribution. They are pelagic through most of the year.

The population in the Ross Sea may number 500 (Smith *et al,.* 2012) to 5000 individuals (Waterhouse 2001; Ainley 2010; Pinkerton and Bradford-Grieve 2010). According to surveys by Bester *et al.* (2006), Ross seals are relatively abundant in the Ross Sea. Based on surveys of the Ross and Amundsen seas, Bengtson *et al.* (2011) estimated an abundance of 22,600, with the highest density (0.032 seals/km^2) in deep water (greater than 3000 m) within 200 km from the ice edge; low densities were estimated for the proposed survey area. Ross seals were seen in the western (Stirling 1969) and eastern Ross Sea during surveys (Stirling 1969; Ackley *et al.,* 2003; Bester and Stewart 2006). During an NSF-funded seismic survey in the Ross Sea in January through February 2015, two sightings of single Ross seals were made to the east of the proposed survey area (RPS 2015a).

Weddell Seal

The Weddell seal is the second most abundant species of Antarctic seal (Hückstädt 2018a). It occurs in the fast

and pack ice around all of Antarctica, as well as on land along the coast, but is rarely found in ice-free water (Hückstädt 2018a). It occurs on the Ross Sea shelf and slope (Ballard *et al.,* 21012). It is the most southerly breeding mammal in the world, occurring as far south as the RIS (Hückstädt 2018a). Unlike other Antarctic ice seals, Weddell seals form colonies (Cameron *et al.,* 2007). There are numerous pupping locations throughout the western Ross Sea, including around Ross Island (Ainley *et al.,* 2010). Juveniles tend to disperse widely, resulting in genetic diversity in the population (Hückstädt 2018a). Seals outfitted with tags in the western Ross Sea were documented to disperse hundreds of kilometers, making their way into the proposed survey areas (Ainley *et al.,* 2010; Goetz 2015). However, some small colonies have been isolated from open water by ice sheets and therefore show inbreeding depression (Gelatt *et al.,* 2010). Weddell seals primarily feed on fish. Pups are born from October through November and are weaned after ~six to eight weeks (Hückstädt 2018a). Paterson *et al.* (2015) suggested that the timing of reproduction by Weddell seals in Erebus Bay, McMurdo Sound, is coupled with periods of high productivity in Ross Bay. After the breeding season, the ice breaks down and seals disperse into the sea to forage for one to two months and return to ice or land to molt in January and February (Hückstädt 2018a).

Ainley *et al.* (2010) estimated that 50 to 72 percent of the South Pacific sector of Weddell seals occur in the Ross Sea. The population in the Ross Sea has been estimated between 32,000 and 50,000 individuals (*e.g.,* Ainley 2002, 2010; Pinkerton and Bradford-Grieve 2010; Smith *et al.,* 2012). Bengtson *et al.* (2011) estimated the population in the Ross and Amundsen seas at 330,000 seals. The highest densities (up to 0.173 seals/km^2) were observed in water less than 3000 m deep; densities in the proposed survey area were estimated to be lower (Bengtson *et al.,* 2011). Populations at McMurdo Sound were permanently reduced by sealing in the 20th century (Ainley 2010). Sightings within the Ross Sea, including within and near the proposed survey area, have been reported by several sources (Stirling 1969; Saino and Guglielmo 2002; Ackley *et al.,* 2003; Van Dam and Kooyman 2004; Bester and Stewart 2006; Ainley *et al.,* 2010; Ropert-Coudert *et al.,* 2014; Baird and Mormede 2014). Ballard *et al.* (2012) relatively low habitat suitability for Weddell seals in the majority of the Ross Bank survey area, with higher suitability in the eastern portion of the Ross Bank survey area and within the Drygalski Trough survey area. During an NSF-funded seismic survey in the Ross Sea in January through February 2015, 17 sightings of Weddell seals were made, including within the proposed survey area (RPS 2015a).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.,* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth & Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Description of Active Acoustic Sound Sources

This section contains a brief technical background on sound, the characteristics of certain sound types, and on metrics used in this proposal in as much as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness'' of a sound and is typically described using the relative unit of the dB. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is one microPascal (μPa)) and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of one m from the source (referenced to one μPa) while the received level is the SPL at the listener's position (referenced to one μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings & Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 μPa^2-s) represents the total energy contained within a pulse and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (pk-pk), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately six dB higher than peak pressure (Southall *et al.,* 2007).

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam or beams or may radiate in all directions (omnidirectional sources), as is the case for pulses produced by the airgun arrays considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound. Ambient sound is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995), and the sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including the following (Richardson *et al.,* 1995):

(1) Wind and waves: The complex interactions between wind and water surface, including processes such as breaking waves and wave-induced bubble oscillations and cavitation, are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Surf sound becomes important near shore, with measurements collected at a distance of 8.5 km from shore showing an increase of 10 dB in the 100 to 700 Hz band during heavy surf conditions;

(2) Precipitation: Sound from rain and hail impacting the water surface can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times;

(3) Biological: Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz; and

(4) Anthropogenic: Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, seismic surveys, sonar, explosions, and ocean acoustic studies. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below one kHz and, if higher frequency sound levels are created, they attenuate rapidly. Sound from identifiable anthropogenic sources other than the activity of interest (*e.g.,* a passing vessel) is sometimes termed background sound, as opposed to ambient sound.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from a given activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals. Details of source types are described in the following text.

Sounds are often considered to fall into one of two general types: pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts.

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms,

impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Airgun arrays produce pulsed signals with energy in a frequency range from about 10–2,000 Hz, with most energy radiated at frequencies below 200 Hz. The amplitude of the acoustic wave emitted from the source is equal in all directions (*i.e.,* omnidirectional), but airgun arrays do possess some directionality due to different phase delays between guns in different directions. Airgun arrays are typically tuned to maximize functionality for data acquisition purposes, meaning that sound transmitted in horizontal directions and at higher frequencies is minimized to the extent possible.

As described above, hull-mounted MBESs, SBP, and ADCPs would also be operated from vessel continuously throughout the seismic surveys. Given the higher frequencies and relatively narrow beampatterns associated with these sources, in context of the movement and speed of the vessel, exposures of marine mammals are considered unlikely and, therefore, we do not expect take of marine mammals to result from use of these sources and do not consider them further in this analysis.

Acoustic Effects

Here, we discuss the effects of active acoustic sources on marine mammals.

Potential Effects of Underwater Sound—Please refer to the information given previously (*Description of Active Acoustic Sound Sources* section) regarding sound, characteristics of sound types, and metrics used in this document. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to the use of airgun arrays.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal, but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We describe the more severe effects of certain non-auditory physical or physiological effects only briefly as we do not expect that use of airgun arrays are reasonably likely to result in such effects (see below for further discussion). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.,* 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer & Tyack, 2007; Tal *et al.,* 2015). The survey activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects.

Threshold Shift—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several dBs above (a 40-dB threshold shift approximates PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset;

e.g., Southall *et al.,* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as airgun pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

For mid-frequency cetaceans in particular, potential protective mechanisms may help limit onset of TTS or prevent onset of PTS. Such mechanisms include dampening of hearing, auditory adaptation, or behavioral amelioration (*e.g.,* Nachtigall and Supin, 2013; Miller *et al.,* 2012; Finneran *et al.,* 2015; Popov *et al.,* 2016).

TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts.

Finneran *et al.* (2015) measured hearing thresholds in three captive bottlenose dolphins before and after exposure to ten pulses produced by a seismic airgun in order to study TTS induced after exposure to multiple pulses. Exposures began at relatively low levels and gradually increased over a period of several months, with the highest exposures at peak SPLs from 196 to 210 dB and cumulative (unweighted) SELs from 193–195 dB. No substantial TTS was observed. In addition, behavioral reactions were observed that indicated that animals can learn behaviors that effectively mitigate noise exposures (although exposure patterns must be learned, which is less likely in wild animals than for the captive animals considered in this study). The authors note that the failure to induce more significant auditory effects is likely due to the intermittent nature of exposure, the relatively low peak pressure produced by the acoustic source, and the low-frequency energy in airgun pulses as compared with the frequency range of best sensitivity for dolphins and other mid-frequency cetaceans.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale, harbor porpoise, and Yangtze finless porpoise) exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). In general, harbor porpoises have a lower TTS onset than other measured cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes.

Critical questions remain regarding the rate of TTS growth and recovery after exposure to intermittent noise and the effects of single and multiple pulses. Data at present are also insufficient to construct generalized models for recovery and determine the time necessary to treat subsequent exposures as independent events. More information is needed on the relationship between auditory evoked potential and behavioral measures of TTS for various stimuli. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and NMFS (2018).

Behavioral Effects—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton & Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007). However, many delphinids approach acoustic source vessels with no apparent discomfort or

obvious behavioral change (*e.g.,* Barkaszi *et al.,* 2012).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau & Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely, and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel & Clark, 2000; Ng & Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a, b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.;* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Visual tracking, passive acoustic monitoring, and movement recording tags were used to quantify sperm whale behavior prior to, during, and following exposure to airgun arrays at received levels in the range 140–160 dB at distances of 7–13 km, following a phase-in of sound intensity and full array exposures at 1–13 km (Madsen *et al.,* 2006; Miller *et al.,* 2009). Sperm whales did not exhibit horizontal avoidance behavior at the surface. However, foraging behavior may have been affected. The sperm whales exhibited 19 percent less vocal (buzz) rate during full exposure relative to post exposure, and the whale that was approached most closely had an extended resting period and did not resume foraging until the airguns had ceased firing. The remaining whales continued to execute foraging dives throughout exposure; however, swimming movements during foraging dives were six percent lower during exposure than control periods (Miller *et al.,* 2009). These data raise concerns that seismic surveys may impact foraging behavior in sperm whales, although more data are required to understand whether the differences were due to exposure or natural variation in sperm whale behavior (Miller *et al.,* 2009).

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007, 2016).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Cerchio *et al.* (2014) used passive acoustic monitoring to document the presence of singing humpback whales off the coast of northern Angola and to opportunistically test for the effect of seismic survey activity on the number of singing whales. Two recording units were deployed between March and December 2008 in the offshore environment; numbers of singers were counted every hour. Generalized Additive Mixed Models were used to assess the effect of survey day (seasonality), hour (diel variation), moon phase, and received levels of noise (measured from a single pulse during each 10 minute sampled period) on singer number. The number of singers significantly decreased with increasing received level of noise, suggesting that humpback whale breeding activity was disrupted to some extent by the survey activity.

Castellote *et al.* (2012) reported acoustic and behavioral changes by fin whales in response to shipping and airgun noise. Acoustic features of fin whale song notes recorded in the Mediterranean Sea and northeast Atlantic Ocean were compared for areas with different shipping noise levels and traffic intensities and during a seismic airgun survey. During the first 72 h of the survey, a steady decrease in song received levels and bearings to singers indicated that whales moved away from the acoustic source and out of the study area. This displacement persisted for a time period well beyond the 10-day duration of seismic airgun activity, providing evidence that fin whales may avoid an area for an extended period in the presence of increased noise. The authors hypothesize that fin whale acoustic communication is modified to compensate for increased background noise and that a sensitization process may play a role in the observed temporary displacement.

Seismic pulses at average received levels of 131 dB re 1 μPa^2-s caused blue whales to increase call production (Di Iorio and Clark, 2010). In contrast, McDonald *et al.* (1995) tracked a blue whale with seafloor seismometers and reported that it stopped vocalizing and changed its travel direction at a range of 10 km from the acoustic source vessel (estimated received level 143 dB pk-pk). Blackwell *et al.* (2013) found that

bowhead whale call rates dropped significantly at onset of airgun use at sites with a median distance of 41–45 km from the survey. Blackwell *et al.* (2015) expanded this analysis to show that whales actually increased calling rates as soon as airgun signals were detectable before ultimately decreasing calling rates at higher received levels (*i.e.,* 10-minute SEL_{cum} of ~127 dB). Overall, these results suggest that bowhead whales may adjust their vocal output in an effort to compensate for noise before ceasing vocalization effort and ultimately deflecting from the acoustic source (Blackwell *et al.,* 2013, 2015). These studies demonstrate that even low levels of noise received far from the source can induce changes in vocalization and/or behavior for mysticetes.

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.,* 1984). Humpback whales showed avoidance behavior in the presence of an active seismic array during observational studies and controlled exposure experiments in western Australia (McCauley *et al.,* 2000). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor & Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans & England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford & Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp & Livoreil, 1997; Fritz *et al.,* 2002; Purser & Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington & Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Stone (2015) reported data from at-sea observations during 1,196 seismic surveys from 1994 to 2010. When large arrays of airguns (considered to be 500 in^3 or more) were firing, lateral displacement, more localized avoidance, or other changes in behavior were evident for most odontocetes. However, significant responses to large arrays were found only for the minke whale and fin whale. Behavioral responses observed included changes in swimming or surfacing behavior, with indications that cetaceans remained near the water surface at these times. Cetaceans were recorded as feeding less often when large arrays were active. Behavioral observations of gray whales during a seismic survey monitored whale movements and respirations pre-, during and post-seismic survey (Gailey *et al.,* 2016). Behavioral state and water depth were the best 'natural' predictors of whale movements and respiration and, after considering natural variation, none of the response variables were significantly associated with seismic survey or vessel sounds.

Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last

until the animal replenishes its energetic reserves sufficiently to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair & Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Auditory Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited, although there are few specific data on this. Because of the intermittent nature and low duty cycle of seismic pulses, animals can emit and receive sounds in the relatively quiet intervals between pulses. However, in exceptional situations, reverberation occurs for much or all of the interval between pulses (*e.g.,* Simard *et al.,* 2005; Clark & Gagnon 2006), which could mask calls. Situations with prolonged strong reverberation are infrequent. However, it is common for reverberation to cause some lesser degree of elevation of the background level between airgun pulses (*e.g.,* Gedamke 2011; Guerra *et al.,* 2011, 2016; Klinck *et al.,* 2012; Guan *et al.,* 2015), and this weaker reverberation presumably reduces the detection range of calls and other natural sounds to some degree. Guerra *et al.* (2016) reported that ambient noise levels between seismic pulses were elevated as a result of reverberation at ranges of 50 km from the seismic source. Based on measurements in deep water of the Southern Ocean, Gedamke (2011) estimated that the slight elevation of background levels during intervals between pulses reduced blue and fin whale communication space by as much as 36–51 percent when a seismic survey was operating 450–2,800 km away. Based on preliminary modeling, Wittekind *et al.* (2016) reported that airgun sounds could reduce the communication range of blue and fin whales 2000 km from the seismic source. Nieukirk *et al.* (2012) and Blackwell *et al.* (2015) noted the potential for masking effects from seismic surveys on large whales.

Some baleen and toothed whales are known to continue calling in the presence of seismic pulses, and their calls usually can be heard between the pulses (*e.g.,* Nieukirk *et al.,* 2012; Thode *et al.,* 2012; Bröker *et al.,* 2013; Sciacca *et al.,* 2016). As noted above, Cerchio *et al.* (2014) suggested that the breeding display of humpback whales off Angola could be disrupted by seismic sounds, as singing activity declined with increasing received levels. In addition, some cetaceans are known to change their calling rates, shift their peak frequencies, or otherwise modify their vocal behavior in response to airgun sounds (*e.g.,* Di Iorio and Clark 2010; Castellote *et al.,* 2012; Blackwell *et al.,* 2013, 2015). The hearing systems of baleen whales are undoubtedly more sensitive to low-frequency sounds than are the ears of the small odontocetes that have been studied directly (*e.g.,* MacGillivray *et al.,* 2014). The sounds important to small odontocetes are

predominantly at much higher frequencies than are the dominant components of airgun sounds, thus limiting the potential for masking. In general, masking effects of seismic pulses are expected to be minor, given the normally intermittent nature of seismic pulses.

Icebreaking

Icebreakers produce more noise while breaking ice than ships of comparable size due, primarily, to the sounds of propeller cavitation (Richardson *et al.,* 1995). Icebreakers commonly back and ram into heavy ice until losing momentum to make way. The highest noise levels usually occur while backing full astern in preparation to ram forward through the ice. Overall the noise generated by an icebreaker pushing ice was 10 to 15 dB greater than the noise produced by the ship underway in open water (Richardson *et al.,* 1995). In general, the Antarctic and Southern Ocean is a noisy environment. Calving and grounding icebergs as well as the break-up of ice sheets, can produce a large amount of underwater noise. Little information is available about the increased sound levels due to icebreaking.

Cetaceans—Few studies have been conducted to evaluate the potential interference of icebreaking noise with marine mammal vocalizations. Erbe and Farmer (1998) measured masked hearing thresholds of a captive beluga whale. They reported that the recording of a Canadian Coast Guard Ship (CCGS) *Henry Larsen,* ramming ice in the Beaufort Sea, masked recordings of beluga vocalizations at a noise to signal pressure ratio of 18 dB, when the noise pressure level was eight times as high as the call pressure. Erbe and Farmer (2000) also predicted when icebreaker noise would affect beluga whales through software that combined a sound propagation model and beluga whale impact threshold models. They again used the data from the recording of the *Henry Larsen* in the Beaufort Sea and predicted that masking of beluga whale vocalizations could extend between 40 and 71 km (21.6 and 38.3 nmi) near the surface. Lesage *et al.* (1999) report that beluga whales changed their call type and call frequency when exposed to boat noise. It is possible that the whales adapt to the ambient noise levels and are able to communicate despite the sound. Given the documented reaction of belugas to ships and icebreakers it is highly unlikely that beluga whales would remain in the proximity of vessels where vocalizations would be masked.

Beluga whales have been documented swimming rapidly away from ships and icebreakers in the Canadian high Arctic when a ship approaches to within 35 to 50 km (18.9 to 27 nmi), and they may travel up to 80 km (43.2 nmi) from the vessel's track (Richardson *et al.,* 1995). It is expected that belugas avoid icebreakers as soon as they detect the ships (Cosens and Dueck, 1993). However, the reactions of beluga whales to ships vary greatly and some animals may become habituated to high levels of ambient noise (Erbe and Farmer, 2000).

There is little information about the effects of icebreaking ships on baleen whales. Migrating bowhead whales appeared to avoid an area around a drill site by greater than 25 km (13.5 mi) where an icebreaker was working in the Beaufort Sea. There was intensive icebreaking daily in support of the drilling activities (Brewer *et al.,* 1993). Migrating bowheads also avoided a nearby drill site at the same time of year where little icebreaking was being conducted (LGL and Greeneridge, 1987). It is unclear as to whether the drilling activities, icebreaking operations, or the ice itself might have been the cause for the whale's diversion. Bowhead whales are not expected to occur in the proximity of the proposed action area.

Pinnipeds—Brueggeman *et al.* (1992) reported on the reactions of seals to an icebreaker during activities at two prospects in the Chukchi Sea. Reactions of seals to the icebreakers varied between the two prospects. Most (67 percent) seals did not react to the icebreaker at either prospect. Reaction at one prospect was greatest during icebreaking activity (running/maneuvering/jogging) and was 0.23 km (0.12 nmi) of the vessel and lowest for animals beyond 0.93 km (0.5 nmi). At the second prospect however, seal reaction was lowest during icebreaking activity with higher and similar levels of response during general (non-icebreaking) vessel operations and when the vessel was at anchor or drifting. The frequency of seal reaction generally declined with increasing distance from the vessel except during general vessel activity where it remained consistently high to about 0.46 km (0.25 nmi) from the vessel before declining.

Similarly, Kanik *et al.* (1980) found that ringed (*Pusa hispida*) and harp seals (*Pagophilus groenlandicus*) often dove into the water when an icebreaker was breaking ice within 1 km (0.5 nmi) of the animals. Most seals remained on the ice when the ship was breaking ice 1 to 2 km (0.5 to 1.1 nmi) away.

Sea ice is important for pinniped life functions such as resting, breeding, and molting. Icebreaking activities may damage seal breathing holes and would also reduce the haulout area in the immediate vicinity of the ship's track. Icebreaking along a maximum of 500 km of tracklines would alter local ice conditions in the immediate vicinity of the vessel. This has the potential to temporarily lead to a reduction of suitable seal haulout habitat. However, the dynamic sea-ice environment requires that seals be able to adapt to changes in sea, ice, and snow conditions, and they therefore create new breathing holes and lairs throughout the winter and spring (Hammill and Smith, 1989). In addition, seals often use open leads and cracks in the ice to surface and breathe (Smith and Stirling, 1975). Disturbance of the ice would occur in a very small area relative to the Southern Ocean ice-pack and no significant impact on marine mammals is anticipated by icebreaking during the proposed low-energy seismic survey.

Ship Noise

Vessel noise from the RVIB *Palmer* could affect marine animals in the proposed survey areas. Houghton *et al.* (2015) proposed that vessel speed is the most important predictor of received noise levels, and Putland *et al.* (2017) also reported reduced sound levels with decreased vessel speed. Sounds produced by large vessels generally dominate ambient noise at frequencies from 20 to 300 Hz (Richardson *et al.,* 1995). However, some energy is also produced at higher frequencies (Hermannsen *et al.,* 2014); low levels of high-frequency sound from vessels has been shown to elicit responses in harbor porpoise (Dyndo *et al.,* 2015). Increased levels of ship noise have been shown to affect foraging by porpoise (Teilmann *et al.,* 2015; Wisniewska *et al.,* 2018); Wisniewska *et al.* (2018) suggest that a decrease in foraging success could have long-term fitness consequences.

Ship noise, through masking, can reduce the effective communication distance of a marine mammal if the frequency of the sound source is close to that used by the animal, and if the sound is present for a significant fraction of time (*e.g.,* Richardson *et al.,* 1995; Clark *et al,.* 2009; Jensen *et al.,* 2009; Gervaise *et al.,* 2012; Hatch *et al.,* 2012; Rice *et al.,* 2014; Dunlop 2015; Erbe *et al.,* 2016; Jones *et al,.* 2017; Putland *et al.,* 2017). In addition to the frequency and duration of the masking sound, the strength, temporal pattern, and location of the introduced sound also play a role in the extent of the masking (Branstetter *et al.,* 2013, 2016; Finneran and Branstetter 2013; Sills *et al.,* 2017). Branstetter *et al.* (2013)

reported that time-domain metrics are also important in describing and predicting masking. In order to compensate for increased ambient noise, some cetaceans are known to increase the source levels of their calls in the presence of elevated noise levels from shipping, shift their peak frequencies, or otherwise change their vocal behavior (*e.g.,* Parks *et al.,* 2011, 2012, 2016a,b; Castellote *et al.,* 2012; Melcón *et al.,* 2012; Azzara *et al.,* 2013; Tyack and Janik 2013; Luís *et al.,* 2014; Sairanen 2014; Papale *et al.,* 2015; Bittencourt *et al.,* 2016; Dahlheim and Castellote 2016; Gospić and Picciulin 2016; Gridley *et al.,* 2016; Heiler *et al.,* 2016; Martins *et al.,* 2016; O'Brien *et al.,* 2016; Tenessen & Parks 2016). Harp seals did not increase their call frequencies in environments with increased low-frequency sounds (Terhune and Bosker 2016). Holt *et al.* (2015) reported that changes in vocal modifications can have increased energetic costs for individual marine mammals. A negative correlation between the presence of some cetacean species and the number of vessels in an area has been demonstrated by several studies (*e.g.,* Campana *et al.,* 2015; Culloch *et al.,* 2016).

Baleen whales are thought to be more sensitive to sound at these low frequencies than are toothed whales (*e.g.,* MacGillivray *et al.,* 2014), possibly causing localized avoidance of the proposed survey area during seismic operations. Reactions of gray and humpback whales to vessels have been studied, and there is limited information available about the reactions of right whales and rorquals (fin, blue, and minke whales). Reactions of humpback whales to boats are variable, ranging from approach to avoidance (Payne 1978; Salden 1993). Baker *et al.* (1982, 1983) and Baker and Herman (1989) found humpbacks often move away when vessels are within several kilometers. Humpbacks seem less likely to react overtly when actively feeding than when resting or engaged in other activities (Krieger and Wing 1984, 1986). Increased levels of ship noise have been shown to affect foraging by humpback whales (Blair *et al.,* 2016). Fin whale sightings in the western Mediterranean were negatively correlated with the number of vessels in the area (Campana *et al.,* 2015). Minke whales and gray seals have shown slight displacement in response to construction-related vessel traffic (Anderwald *et al.,* 2013).

Many odontocetes show considerable tolerance of vessel traffic, although they sometimes react at long distances if confined by ice or shallow water, if previously harassed by vessels, or if they have had little or no recent exposure to ships (Richardson *et al.,* 1995). Dolphins of many species tolerate and sometimes approach vessels (*e.g.,* Anderwald *et al.,* 2013). Some dolphin species approach moving vessels to ride the bow or stern waves (Williams *et al.,* 1992). Pirotta *et al.* (2015) noted that the physical presence of vessels, not just ship noise, disturbed the foraging activity of bottlenose dolphins. Sightings of striped dolphin, Risso's dolphin, sperm whale, and Cuvier's beaked whale in the western Mediterranean were negatively correlated with the number of vessels in the area (Campana *et al.,* 2015).

There are few data on the behavioral reactions of beaked whales to vessel noise, though they seem to avoid approaching vessels (*e.g.,* Würsig *et al.,* 1998) or dive for an extended period when approached by a vessel (*e.g.,* Kasuya 1986). Based on a single observation, Aguilar Soto *et al.* (2006) suggest foraging efficiency of Cuvier's beaked whales may be reduced by close approach of vessels.

Sounds emitted by the *Palmer* are low frequency and continuous, but would be widely dispersed in both space and time. Project vessel sounds would not be at levels expected to cause anything more than possible localized and temporary behavioral changes in marine mammals, and would not be expected to result in significant negative effects on individuals or at the population level. In addition, in all oceans of the world, large vessel traffic is currently so prevalent that it is commonly considered a usual source of ambient sound (NSF–USGS 2011).

In summary, project vessel sounds would not be at levels expected to cause anything more than possible localized and temporary behavioral changes in marine mammals, and would not be expected to result in significant negative effects on individuals or at the population level.

Ship Strike

Vessel collisions with marine mammals, or ship strikes, can result in death or serious injury of the animal. Wounds resulting from ship strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus, 2001). An animal at the surface may be struck directly by a vessel, a surfacing animal may hit the bottom of a vessel, or an animal just below the surface may be cut by a vessel's propeller. Superficial strikes may not kill or result in the death of the animal. These interactions are typically associated with large whales (*e.g.,* fin whales), which are occasionally found draped across the bulbous bow of large commercial ships upon arrival in port. Although smaller cetaceans are more maneuverable in relation to large vessels than are large whales, they may also be susceptible to strike. The severity of injuries typically depends on the size and speed of the vessel, with the probability of death or serious injury increasing as vessel speed increases (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007; Conn and Silber, 2013). Impact forces increase with speed, as does the probability of a strike at a given distance (Silber *et al.,* 2010; Gende *et al.,* 2011).

Pace and Silber (2005) also found that the probability of death or serious injury increased rapidly with increasing vessel speed. Specifically, the predicted probability of serious injury or death increased from 45 to 75 percent as vessel speed increased from 10 to 14 kn, and exceeded 90 percent at 17 kn. Higher speeds during collisions result in greater force of impact, but higher speeds also appear to increase the chance of severe injuries or death through increased likelihood of collision by pulling whales toward the vessel (Clyne, 1999; Knowlton *et al.,* 1995). In a separate study, Vanderlaan and Taggart (2007) analyzed the probability of lethal mortality of large whales at a given speed, showing that the greatest rate of change in the probability of a lethal injury to a large whale as a function of vessel speed occurs between 8.6 and 15 kn. The chances of a lethal injury decline from approximately 80 percent at 15 kn to approximately 20 percent at 8.6 kn. At speeds below 11.8 kn, the chances of lethal injury drop below 50 percent, while the probability asymptotically increases toward one hundred percent above 15 kn.

The RVIB *Palmer* travels at a speed of 4.5 kn (8.3 km/hour) when towing seismic survey gear, or at an average speed of 18.7 km/h (10.1 kn) while cruising. At these speeds, both the possibility of striking a marine mammal and the possibility of a strike resulting in serious injury or mortality are discountable. At average transit speed, the probability of serious injury or mortality resulting from a strike is less than 50 percent. However, the likelihood of a strike actually happening is again discountable. Ship strikes, as analyzed in the studies cited above, generally involve commercial shipping, which is much more common in both space and time than is geophysical survey activity. Jensen and Silber (2004) summarized ship strikes of large whales worldwide from 1975–2003 and found that most collisions occurred in the

open ocean and involved large vessels (*e.g.,* commercial shipping). No such incidents were reported for geophysical survey vessels during that time period.

It is possible for ship strikes to occur while traveling at slow speeds. For example, a hydrographic survey vessel traveling at low speed (5.5 kn) while conducting mapping surveys off the central California coast struck and killed a blue whale in 2009. The State of California determined that the whale had suddenly and unexpectedly surfaced beneath the hull, with the result that the propeller severed the whale's vertebrae, and that this was an unavoidable event. This strike represents the only such incident in approximately 540,000 hours of similar coastal mapping activity ($p = 1.9 \times 10^{-6}$; 95 percent CI = 0–5.5×10^{-6}; NMFS, 2013b). In addition, a research vessel reported a fatal strike in 2011 of a dolphin in the Atlantic, demonstrating that it is possible for strikes involving smaller cetaceans to occur. In that case, the incident report indicated that an animal apparently was struck by the vessel's propeller as it was intentionally swimming near the vessel. While indicative of the type of unusual events that cannot be ruled out, neither of these instances represents a circumstance that would be considered reasonably foreseeable or that would be considered preventable.

Although the likelihood of the vessel striking a marine mammal is low, we require a robust ship strike avoidance protocol (see Proposed Mitigation), which we believe eliminates any foreseeable risk of ship strike. We anticipate that vessel collisions involving a seismic data acquisition vessel towing gear, while not impossible, represent unlikely, unpredictable events for which there are no preventive measures. Given the required mitigation measures, the relatively slow speed of the vessel towing gear, the presence of bridge crew watching for obstacles at all times (including marine mammals), and the presence of marine mammal observers, we believe that the possibility of ship strike is discountable and, further, that were a strike of a large whale to occur, it would be unlikely to result in serious injury or mortality. No incidental take resulting from ship strike is anticipated, and this potential effect of the specified activity will not be discussed further in the following analysis.

Stranding—When a living or dead marine mammal swims or floats onto shore and becomes ''beached'' or incapable of returning to sea, the event is a ''stranding'' (Geraci *et al.,* 1999; Perrin and Geraci, 2002; Geraci and Lounsbury, 2005; NMFS, 2007). The legal definition for a ''stranding'' under the MMPA is an event in the wild in which (A) a marine mammal is dead and is (i) on a beach or shore of the United States; or (ii) in waters under the jurisdiction of the United States (including any navigable waters); or (B) a marine mammal is alive and is (i) on a beach or shore of the United States and unable to return to the water; (ii) on a beach or shore of the United States and, although able to return to the water, is in need of apparent medical attention; or (iii) in the waters under the jurisdiction of the United States (including any navigable waters), but is unable to return to its natural habitat under its own power or without assistance (16 U.S.C. 1421h(3)).

Marine mammals strand for a variety of reasons, such as infectious agents, biotoxicosis, starvation, fishery interaction, ship strike, unusual oceanographic or weather events, sound exposure, or combinations of these stressors sustained concurrently or in series. However, the cause or causes of most strandings are unknown (Geraci *et al.,* 1976; Eaton, 1979; Odell *et al.,* 1980; Best, 1982). Numerous studies suggest that the physiology, behavior, habitat relationships, age, or condition of cetaceans may cause them to strand or might pre-dispose them to strand when exposed to another phenomenon. These suggestions are consistent with the conclusions of numerous other studies that have demonstrated that combinations of dissimilar stressors commonly combine to kill an animal or dramatically reduce its fitness, even though one exposure without the other does not produce the same result (Chrousos, 2000; Creel, 2005; DeVries *et al.,* 2003; Fair & Becker, 2000; Foley *et al.,* 2001; Moberg, 2000; Relyea, 2005a; 2005b, Romero, 2004; Sih *et al.,* 2004).

There is no conclusive evidence that exposure to airgun noise results in behaviorally-mediated forms of injury. Behaviorally-mediated injury (*i.e.,* mass stranding events) has been primarily associated with beaked whales exposed to mid-frequency active (MFA) naval sonar. Tactical sonar and the alerting stimulus used in Nowacek *et al.* (2004) are very different from the noise produced by airguns. One should therefore not expect the same reaction to airgun noise as to these other sources. As explained below, military MFA sonar is very different from airguns, and one should not assume that airguns will cause the same effects as MFA sonar (including strandings).

To understand why Navy MFA sonar affects beaked whales differently than airguns do, it is important to note the distinction between behavioral sensitivity and susceptibility to auditory injury. To understand the potential for auditory injury in a particular marine mammal species in relation to a given acoustic signal, the frequency range the species is able to hear is critical, as well as the species' auditory sensitivity to frequencies within that range. Current data indicate that not all marine mammal species have equal hearing capabilities across all frequencies and, therefore, species are grouped into hearing groups with generalized hearing ranges assigned on the basis of available data (Southall *et al.,* 2007, 2019). Hearing ranges as well as auditory sensitivity/susceptibility to frequencies within those ranges vary across the different groups. For example, in terms of hearing range, the high-frequency cetaceans (*e.g., Kogia* spp.) have a generalized hearing range of frequencies between 275 Hz and 160 kHz, while mid-frequency cetaceans—such as dolphins and beaked whales—have a generalized hearing range between 150 Hz to 160 kHz. Regarding auditory susceptibility within the hearing range, while mid-frequency cetaceans and high-frequency cetaceans have roughly similar hearing ranges, the high-frequency group is much more susceptible to noise-induced hearing loss during sound exposure, *i.e.,* these species have lower thresholds for these effects than other hearing groups (NMFS, 2018). Referring to a species as behaviorally sensitive to noise simply means that an animal of that species is more likely to respond to lower received levels of sound than an animal of another species that is considered less behaviorally sensitive. So, while dolphin species and beaked whale species—both in the mid-frequency cetacean hearing group—are assumed to generally hear the same sounds equally well and be equally susceptible to noise-induced hearing loss (auditory injury), the best available information indicates that a beaked whale is more likely to behaviorally respond to that sound at a lower received level compared to an animal from other mid-frequency cetacean species that are less behaviorally sensitive. This distinction is important because, while beaked whales are more likely to respond behaviorally to sounds than are many other species (even at lower levels), they cannot hear the predominant, lower frequency sounds from seismic airguns as well as sounds that have more energy at frequencies that beaked whales can hear better (such as military MFA sonar).

Navy MFA sonar affects beaked whales differently than airguns do because it produces energy at different frequencies than airguns. Mid-frequency cetacean hearing is generically thought to be best between 8.8 to 110 kHz, *i.e.,* these cutoff values define the range above and below which a species in the group is assumed to have declining auditory sensitivity, until reaching frequencies that cannot be heard (NMFS, 2018). However, beaked whale hearing is likely best within a higher, narrower range (20–80 kHz, with best sensitivity around 40 kHz), based on a few measurements of hearing in stranded beaked whales (Cook *et al.,* 2006; Finneran *et al.,* 2009; Pacini *et al.,* 2011) and several studies of acoustic signals produced by beaked whales (*e.g.,* Frantzis *et al.,* 2002; Johnson *et al.,* 2004, 2006; Zimmer *et al.,* 2005). While precaution requires that the full range of audibility be considered when assessing risks associated with noise exposure (Southall *et al.,* 2007, 2019a, 2019), animals typically produce sound at frequencies where they hear best. More recently, Southall *et al.* (2019) suggested that certain species in the historical mid-frequency hearing group (beaked whales, sperm whales, and killer whales) are likely more sensitive to lower frequencies within the group's generalized hearing range than are other species within the group, and state that the data for beaked whales suggest sensitivity to approximately 5 kHz. However, this information is consistent with the general conclusion that beaked whales (and other mid-frequency cetaceans) are relatively insensitive to the frequencies where most energy of an airgun signal is found. Military MFA sonar is typically considered to operate in the frequency range of approximately 3–14 kHz (D'Amico *et al.,* 2009), *i.e.,* outside the range of likely best hearing for beaked whales but within or close to the lower bounds, whereas most energy in an airgun signal is radiated at much lower frequencies, below 500 Hz (Dragoset, 1990).

It is important to distinguish between energy (loudness, measured in dB) and frequency (pitch, measured in Hz). In considering the potential impacts of mid-frequency components of airgun noise (1–10 kHz, where beaked whales can be expected to hear) on marine mammal hearing, one needs to account for the energy associated with these higher frequencies and determine what energy is truly ''significant.'' Although there is mid-frequency energy associated with airgun noise (as expected from a broadband source), airgun sound is predominantly below 1 kHz (Breitzke *et al.,* 2008; Tashmukhambetov *et al.,* 2008; Tolstoy *et al.,* 2009). As stated by Richardson *et al.* (1995), ''[. . .] most emitted [seismic airgun] energy is at 10–120 Hz, but the pulses contain some energy up to 500–1,000 Hz.'' Tolstoy *et al.* (2009) conducted empirical measurements, demonstrating that sound energy levels associated with airguns were at least 20 decibels (dB) lower at 1 kHz (considered ''mid-frequency'') compared to higher energy levels associated with lower frequencies (below 300 Hz) (''all but a small fraction of the total energy being concentrated in the 10–300 Hz range'' [Tolstoy *et al.,* 2009]), and at higher frequencies (*e.g.,* 2.6–4 kHz), power might be less than 10 percent of the peak power at 10 Hz (Yoder, 2002). Energy levels measured by Tolstoy *et al.* (2009) were even lower at frequencies above 1 kHz. In addition, as sound propagates away from the source, it tends to lose higher-frequency components faster than low-frequency components (*i.e.,* low-frequency sounds typically propagate longer distances than high-frequency sounds) (Diebold *et al.,* 2010). Although higher-frequency components of airgun signals have been recorded, it is typically in surface-ducting conditions (*e.g.,* DeRuiter *et al.,* 2006; Madsen *et al.,* 2006) or in shallow water, where there are advantageous propagation conditions for the higher frequency (but low-energy) components of the airgun signal (Hermannsen *et al.,* 2015). This should not be of concern because the likely behavioral reactions of beaked whales that can result in acute physical injury would result from noise exposure at depth (because of the potentially greater consequences of severe behavioral reactions). In summary, the frequency content of airgun signals is such that beaked whales will not be able to hear the signals well (compared to MFA sonar), especially at depth where we expect the consequences of noise exposure could be more severe.

Aside from frequency content, there are other significant differences between MFA sonar signals and the sounds produced by airguns that minimize the risk of severe behavioral reactions that could lead to strandings or deaths at sea, *e.g.,* significantly longer signal duration, horizontal sound direction, typical fast and unpredictable source movement. All of these characteristics of MFA sonar tend towards greater potential to cause severe behavioral or physiological reactions in exposed beaked whales that may contribute to stranding. Although both sources are powerful, MFA sonar contains significantly greater energy in the mid-frequency range, where beaked whales hear better. Short-duration, high energy pulses—such as those produced by airguns—have greater potential to cause damage to auditory structures (though this is unlikely for mid-frequency cetaceans, as explained later in this document), but it is longer duration signals that have been implicated in the vast majority of beaked whale strandings. Faster, less predictable movements in combination with multiple source vessels are more likely to elicit a severe, potentially anti-predator response. Of additional interest in assessing the divergent characteristics of MFA sonar and airgun signals and their relative potential to cause stranding events or deaths at sea is the similarity between the MFA sonar signals and stereotyped calls of beaked whales' primary predator: the killer whale (Zimmer and Tyack, 2007). Although generic disturbance stimuli—as airgun noise may be considered in this case for beaked whales—may also trigger antipredator responses, stronger responses should generally be expected when perceived risk is greater, as when the stimulus is confused for a known predator (Frid and Dill, 2002). In addition, because the source of the perceived predator (*i.e.,* MFA sonar) will likely be closer to the whales (because attenuation limits the range of detection of mid-frequencies) and moving faster (because it will be on faster-moving vessels), any antipredator response would be more likely to be severe (with greater perceived predation risk, an animal is more likely to disregard the cost of the response; Frid and Dill, 2002). Indeed, when analyzing movements of a beaked whale exposed to playback of killer whale predation calls, Allen *et al.* (2014) found that the whale engaged in a prolonged, directed avoidance response, suggesting a behavioral reaction that could pose a risk factor for stranding. Overall, these significant differences between sound from MFA sonar and the mid-frequency sound component from airguns and the likelihood that MFA sonar signals will be interpreted in error as a predator are critical to understanding the likely risk of behaviorally-mediated injury due to seismic surveys.

The available scientific literature also provides a useful contrast between airgun noise and MFA sonar regarding the likely risk of behaviorally-mediated injury. There is strong evidence for the association of beaked whale stranding events with MFA sonar use, and particularly detailed accounting of several events is available (*e.g.,* a 2000 Bahamas stranding event for which

investigators concluded that MFA sonar use was responsible; Evans and England, 2001). D'Amico *et al.* (2009) reviewed 126 beaked whale mass stranding events over the period from 1950 (*i.e.,* from the development of modern MFA sonar systems) through 2004. Of these, there were two events where detailed information was available on both the timing and location of the stranding and the concurrent nearby naval activity, including verification of active MFA sonar usage, with no evidence for an alternative cause of stranding. An additional ten events were at minimum spatially and temporally coincident with naval activity likely to have included MFA sonar use and, despite incomplete knowledge of timing and location of the stranding or the naval activity in some cases, there was no evidence for an alternative cause of stranding. The U.S. Navy has publicly stated agreement that five such events since 1996 were associated in time and space with MFA sonar use, either by the U.S. Navy alone or in joint training exercises with the North Atlantic Treaty Organization. The U.S. Navy additionally noted that, as of 2017, a 2014 beaked whale stranding event in Crete coincident with naval exercises was under review and had not yet been determined to be linked to sonar activities (U.S. Navy, 2017). Separately, the International Council for the Exploration of the Sea reported in 2005 that, worldwide, there have been about 50 known strandings, consisting mostly of beaked whales, with a potential causal link to MFA sonar (ICES, 2005). In contrast, very few such associations have been made to seismic surveys, despite widespread use of airguns as a geophysical sound source in numerous locations around the world.

A more recent review of possible stranding associations with seismic surveys (Castellote and Llorens, 2016) states plainly that, ''[s]peculation concerning possible links between seismic survey noise and cetacean strandings is available for a dozen events but without convincing causal evidence.'' The authors' ''exhaustive'' search of available information found ten events worth further investigation via a ranking system representing a rough metric of the relative level of confidence offered by the data for inferences about the possible role of the seismic survey in a given stranding event. Only three of these events involved beaked whales. Whereas D'Amico *et al.* (2009) used a 1–5 ranking system, in which ''1'' represented the most robust evidence connecting the event to MFA sonar use, Castellote and Llorens (2016) used a 1–6 ranking system, in which ''6'' represented the most robust evidence connecting the event to the seismic survey. As described above, D'Amico *et al.* (2009) found that two events were ranked ''1'' and ten events were ranked ''2'' (*i.e.,* 12 beaked whale stranding events were found to be associated with MFA sonar use). In contrast, Castellote and Llorens (2016) found that none of the three beaked whale stranding events achieved their highest ranks of 5 or 6. Of the ten total events, none achieved the highest rank of 6. Two events were ranked as 5: one stranding in Peru involving dolphins and porpoises and a 2008 stranding in Madagascar. This latter ranking can only broadly be associated with the survey itself, as opposed to use of seismic airguns. An exhaustive investigation of this stranding event, which did not involve beaked whales, concluded that use of a high-frequency mapping system (12-kHz multibeam echosounder) was the most plausible and likely initial behavioral trigger of the event, which was likely exacerbated by several site- and situation-specific secondary factors. The review panel found that seismic airguns were used after the initial strandings and animals entering a lagoon system, that airgun use clearly had no role as an initial trigger, and that there was no evidence that airgun use dissuaded animals from leaving (Southall *et al.,* 2013).

However, one of these stranding events, involving two Cuvier's beaked whales, was contemporaneous with and reasonably associated spatially with a 2002 seismic survey in the Gulf of California conducted by Lamont-Doherty Earth Observatory (L–DEO), as was the case for the 2007 Gulf of Cadiz seismic survey discussed by Castellote and Llorens (also involving two Cuvier's beaked whales). However, neither event was considered a ''true atypical mass stranding'' (according to Frantzis [1998]) as used in the analysis of Castellote and Llorens (2016). While we agree with the authors that this lack of evidence should not be considered conclusive, it is clear that there is very little evidence that seismic surveys should be considered as posing a significant risk of acute harm to beaked whales or other mid-frequency cetaceans. We have considered the potential for the proposed survey to result in marine mammal stranding and have concluded that, based on the best available information, stranding is not expected to occur.

Use of military tactical sonar has been implicated in a majority of investigated stranding events. Most known stranding events have involved beaked whales, though a small number have involved deep-diving delphinids or sperm whales (*e.g.,* Mazzariol *et al.,* 2010; Southall *et al.,* 2013). In general, long duration (approximately 1 second) and high-intensity sounds (greater than 235 dB SPL) have been implicated in stranding events (Hildebrand, 2004). With regard to beaked whales, mid-frequency sound is typically implicated (when causation can be determined) (Hildebrand, 2004). Although seismic airguns create predominantly low-frequency energy, the signal does include a mid-frequency component. We have considered the potential for the proposed survey to result in marine mammal stranding and have concluded that, based on the best available information, stranding is not expected to occur.

Entanglement—Entanglements occur when marine mammals become wrapped around cables, lines, nets, or other objects suspended in the water column. During seismic operations, numerous cables, lines, and other objects primarily associated with the airgun array and hydrophone streamers will be towed behind the *Palmer* near the water's surface. No incidents of entanglement of marine mammals with seismic survey gear have been documented in over 54,000 kt (100,000 km) of previous NSF-funded seismic surveys when observers were aboard (*e.g.,* Smultea and Holst 2003; Haley and Koski 2004; Holst 2004; Smultea *et al.,* 2004; Holst *et al.,* 2005a; Haley and Ireland 2006; SIO and NSF 2006b; Hauser *et al.,* 2008; Holst and Smultea 2008). Although entanglement with the streamer is theoretically possible, it has not been documented during tens of thousands of miles of NSF-sponsored seismic cruises or, to our knowledge, during hundreds of thousands of miles of industrial seismic cruises. There are a relative few deployed devices, and no interaction between marine mammals and any such device has been recorded during prior NSF surveys using the devices. There are no meaningful entanglement risks posed by the proposed survey, and entanglement risks are not discussed further in this document.

Anticipated Effects on Marine Mammal Habitat

Physical Disturbance—Sources of seafloor disturbance related to geophysical surveys that may impact marine mammal habitat include placement of anchors, nodes, cables, sensors, or other equipment on or in the seafloor for various activities. Equipment deployed on the seafloor has

the potential to cause direct physical damage and could affect bottom-associated fish resources.

Placement of equipment, such as the heat flow probe in the seafloor, could damage areas of hard bottom where direct contact with the seafloor occurs and could crush epifauna (organisms that live on the seafloor or surface of other organisms). Damage to unknown or unseen hard bottom could occur, but because of the small area covered by most bottom-founded equipment and the patchy distribution of hard bottom habitat, contact with unknown hard bottom is expected to be rare and impacts minor. Seafloor disturbance in areas of soft bottom can cause loss of small patches of epifauna and infauna due to burial or crushing, and bottom-feeding fishes could be temporarily displaced from feeding areas. Overall, any effects of physical damage to habitat are expected to be minor and temporary.

Effects to Prey—Marine mammal prey varies by species, season, and location and, for some, is not well documented. Fish react to sounds which are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pulsed sound on fish, although several are based on studies in support of construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Sound pulses at received levels of 160 dB may cause subtle changes in fish behavior. SPLs of 180 dB may cause noticeable changes in behavior (Pearson *et al.,* 1992; Skalski *et al.,* 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality. The most likely impact to fish from survey activities at the project area would be temporary avoidance of the area. The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated.

Marine mammal prey varies by species, season, and location and, for some, is not well documented. Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. However, the reaction of fish to airguns depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Several studies have demonstrated that airgun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017), though the bulk of studies indicate no or slight reaction to noise (*e.g.,* Miller and Cripps, 2013; Dalen and Knutsen, 1987; Pena *et al.,* 2013; Chapman and Hawkins, 1969; Wardle *et al.,* 2001; Sara *et al.,* 2007; Jorgenson and Gyselman, 2009; Blaxter *et al.,* 1981; Cott *et al.,* 2012; Boeger *et al.,* 2006), and that, most commonly, while there are likely to be impacts to fish as a result of noise from nearby airguns, such effects will be temporary. For example, investigators reported significant, short-term declines in commercial fishing catch rate of gadid fishes during and for up to five days after seismic survey operations, but the catch rate subsequently returned to normal (Engas *et al.,* 1996; Engas and Lokkeborg, 2002). Other studies have reported similar findings (Hassel *et al.,* 2004). Skalski *et al.,* (1992) also found a reduction in catch rates—for rockfish (*Sebastes* spp.) in response to controlled airgun exposure—but suggested that the mechanism underlying the decline was not dispersal but rather decreased responsiveness to baited hooks associated with an alarm behavioral response. A companion study showed that alarm and startle responses were not sustained following the removal of the sound source (Pearson *et al.,* 1992). Therefore, Skalski *et al.* (1992) suggested that the effects on fish abundance may be transitory, primarily occurring during the sound exposure itself. In some cases, effects on catch rates are variable within a study, which may be more broadly representative of temporary displacement of fish in response to airgun noise (*i.e.,* catch rates may increase in some locations and decrease in others) than any long-term damage to the fish themselves (Streever *et al.,* 2016).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality and, in some studies, fish auditory systems have been damaged by airgun noise (McCauley *et al.,* 2003; Popper *et al.,* 2005; Song *et al.,* 2008). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b. (2012) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long—both of which are conditions unlikely to occur for this survey that is necessarily transient in any given location and likely result in brief, infrequent noise exposure to prey species in any given area. For this survey, the sound source is constantly moving, and most fish would likely avoid the sound source prior to receiving sound of sufficient intensity to cause physiological or anatomical damage. In addition, ramp-up may allow certain fish species the opportunity to move further away from the sound source.

A recent comprehensive review (Carroll *et al.,* 2017) found that results are mixed as to the effects of airgun noise on the prey of marine mammals. While some studies suggest a change in prey distribution and/or a reduction in prey abundance following the use of seismic airguns, others suggest no effects or even positive effects in prey abundance. As one specific example, Paxton *et al.* (2017), which describes findings related to the effects of a 2014 seismic survey on a reef off of North Carolina, showed a 78 percent decrease in observed nighttime abundance for certain species. It is important to note that the evening hours during which the decline in fish habitat use was recorded (via video recording) occurred on the same day that the seismic survey passed, and no subsequent data is presented to support an inference that the response was long-lasting. Additionally, given that the finding is based on video images, the lack of recorded fish presence does not support a conclusion that the fish actually moved away from the site or suffered any serious impairment. In summary, this particular study corroborates prior studies indicating that a startle response or short-term displacement should be expected.

Available data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Similar to fish, however, the transient nature of

the survey leads to an expectation that effects will be largely limited to behavioral reactions and would occur as a result of brief, infrequent exposures.

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km of the airguns. However, the authors also stated that in order to have significant impacts on r-selected species (*i.e.,* those with high growth rates and that produce many offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011). Most prior research on this topic, which has focused on relatively small spatial scales, has showed minimal effects (*e.g.,* Kostyuchenko, 1973; Booman *et al.,* 1996; Sætre and Ona, 1996; Pearson *et al.,* 1994; Bolle *et al.,* 2012).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.*), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that for copepods with a short life cycle in a high-energy environment, a full-scale airgun survey would impact copepod abundance up to three days following the end of the survey, suggesting that effects such as those found by McCauley *et al.* (2017) would not be expected to be detectable downstream of the survey areas, either spatially or temporally.

Notably, a recently described study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to airgun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 5 m or less from the airguns. Mortality one week after the airgun blast was significantly higher in the copepods placed 10 m from the airgun but was not significantly different from the controls at a distance of 20 m from the airgun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the airgun. Moreover, the authors caution that even this higher mortality in the immediate vicinity of the airguns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sublethal effects on the escape performance or the sensory threshold needed to initiate an escape response at any of the distances from the airgun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 509–658 m, with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 25 m, with no reported mortality at that distance. Regardless, if we assume a worst-case likelihood of severe impacts to zooplankton within approximately 1 km of the acoustic source, the typically wide dispersal of survey vessels and brief time to regeneration of the potentially affected zooplankton populations does not lead us to expect any meaningful follow-on effects to the prey base for odontocete predators.

A recent review article concluded that, while laboratory results provide scientific evidence for high-intensity and low-frequency sound-induced physical trauma and other negative effects on some fish and invertebrates, the sound exposure scenarios in some cases are not realistic to those encountered by marine organisms during routine seismic operations (Carroll *et al.,* 2017). The review finds that there has been no evidence of reduced catch or abundance following seismic activities for invertebrates, and that there is conflicting evidence for fish with catch observed to increase, decrease, or remain the same. Further, where there is evidence for decreased catch rates in response to airgun noise, these findings provide no information about the underlying biological cause of catch rate reduction (Carroll *et al.,* 2017).

In summary, impacts of the specified activity on marine mammal prey species will likely be limited to behavioral responses, the majority of prey species will be capable of moving out of the area during the survey, a rapid return to normal recruitment, distribution, and behavior for prey species is anticipated, and, overall, impacts to prey species will be minor and temporary. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to airgun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in the survey area would be temporary avoidance of the area. The proposed survey would move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once the survey moves out of the area or ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of this survey and the likelihood of temporary avoidance behavior suggest that impacts would be minor.

In general, impacts to marine mammal prey are expected to be limited due to the relatively small temporal and spatial overlap between the proposed survey and any areas used by marine mammal prey species. The proposed use of airguns as part of an active seismic array survey would occur over a relatively short time period (approximately 25 days at sea) and would occur over a very small area relative to the area available as marine mammal habitat in the Ross Sea. We believe any impacts to marine mammals due to adverse effects to their prey would be insignificant due to the limited spatial and temporal impact of the proposed survey. However, adverse impacts may occur to a few species of fish and to zooplankton.

Acoustic Habitat—Acoustic habitat is the soundscape—which encompasses all of the sound present in a particular location and time, as a whole—when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain,

waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are also defined by, and acoustic habitat influenced by, the total contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic, or may be intentionally introduced to the marine environment for data acquisition purposes (as in the use of airgun arrays). Anthropogenic noise varies widely in its frequency content, duration, and loudness and these characteristics greatly influence the potential habitat-mediated effects to marine mammals (please see also the previous discussion on masking under *Acoustic Effects*), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). For more detail on these concepts see, *e.g.,* Barber *et al.,* 2010; Pijanowski *et al.,* 2011; Francis and Barber, 2013; Lillis *et al.,* 2014.

Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). Although the signals emitted by seismic airgun arrays are generally low frequency, they would also likely be of short duration and transient in any given area due to the nature of these surveys. As described previously, exploratory surveys such as this one cover a large area but would be transient rather than focused in a given location over time and therefore would not be considered chronic in any given location.

Based on the information discussed herein, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

All proposed takes are by Level B harassment, involving temporary changes in behavior. No Level A harassment is expected or proposed for authorization. In the sections below, we describe methods to estimate the number of Level B harassment events. The main sources of distributional and numerical data used in deriving the estimates are summarized below.

Generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 µPa (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 µPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

The proposed activities include the use of continuous icebreaking and impulsive seismic sources and, and therefore the 120 and 160 dB re 1 µPa (rms) are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The proposed activity includes the use of impulsive seismic and continuous non-impulsive icebreaking sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For mobile sources (*e.g.,* icebreaking), the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed.

The proposed survey would entail the use of a 2-airgun array with a total discharge of 210 in^3 at a tow depth of 1–4 m (with the worst-case scenario of 4 m assumed for purposes of modeling). L–DEO model results are used to determine the 160 dB_{rms} radius for the 2-airgun array water depth ranging from 150–700 m. Received sound levels were predicted by L–DEO's model (Diebold *et al.,* 2010) as a function of distance from the airguns, for the two 105 in^3 airguns. This modeling approach uses ray tracing for the direct wave traveling from the array to the receiver and its associated source ghost (reflection at the air-water interface in the vicinity of the array), in a constant-velocity half-space (infinite homogenous ocean layer, unbounded by a seafloor). In addition, propagation measurements of pulses from a 36-airgun array at a tow depth of 6 m have been reported in deep water (~1,600 m), intermediate water depth on the slope (~600–1,100 m), and shallow water (~50 m) in the Gulf of Mexico in 2007–2008 (Tolstoy *et al.,* 2009; Diebold *et al.,* 2010).

For deep and intermediate water cases, the field measurements cannot be used readily to derive the Level A and Level B harassment isopleths, as at those sites the calibration hydrophone was located at a roughly constant depth of 350–550 m, which may not intersect all the SPL isopleths at their widest point from the sea surface down to the maximum relevant water depth (~2,000 m) for marine mammals. At short ranges, where the direct arrivals dominate and the effects of seafloor interactions are minimal, the data at the deep sites are suitable for comparison with modeled levels at the depth of the calibration hydrophone. At longer ranges, the comparison with the model—constructed from the maximum SPL through the entire water column at varying distances from the airgun array—is the most relevant.

In deep and intermediate water depths at short ranges, sound levels for direct arrivals recorded by the calibration hydrophone and L–DEO model results for the same array tow depth are in good alignment (see Figures 12 and 14 in Appendix H of NSF–USGS 2011). Consequently, isopleths falling within this domain can be predicted reliably by the L–DEO model, although they may be imperfectly sampled by measurements recorded at a single depth. At greater distances, the calibration data show that seafloor-reflected and sub-seafloor-refracted arrivals dominate, whereas the direct arrivals become weak and/or incoherent (see Figures 11, 12, and 16 in Appendix H of NSF–USGS 2011). Aside from local topography effects, the region around the critical distance is where the observed levels rise closest to the model curve. However, the observed sound levels are found to fall almost entirely below the model curve. Thus, analysis of the Gulf of Mexico calibration measurements demonstrates that although simple, the L–DEO model is a robust tool for conservatively estimating isopleths.

The proposed survey would acquire data with two 105-in^3 guns at a tow depth of 1–4 m. For deep water (>1000 m), we use the deep-water radii obtained from L–DEO model results down to a maximum water depth of 2,000 m for the airgun array. The radii for intermediate water depths (100–1,000 m) are derived from the deep-water ones by applying a correction factor (multiplication) of 1.5, such that observed levels at very near offsets fall below the corrected mitigation curve (see Figure 16 in Appendix H of NSF–USGS 2011).

L–DEO's modeling methodology is described in greater detail in NSF's IHA application. The estimated distances to the Level B harassment isopleth for the

proposed airgun configuration are shown in Table 5.

TABLE 5—PREDICTED RADIAL DISTANCES FROM THE RVIB *Palmer* SEISMIC SOURCE TO ISOPLETHS CORRESPONDING TO LEVEL B HARASSMENT THRESHOLD

Airgun configuration	Water depth (m) [a]	Predicted distances (m) to 160 dB received sound level
Two 105-in^3 GI guns	>1,000	726 [b]
	100–1,000	1,089 [c]

[a] No survey effort would occur in water >1000 m; the distance for this water depth is included for informational purposes only.
[b] Distance is based on L–DEO model results.
[c] Distance is based on L–DEO model results with a 1.5 × correction factor between deep and intermediate water depths.

Table 6 presents the modeled PTS isopleths for each marine mammal hearing group based on the L–DEO modeling incorporated in the companion User Spreadsheet (NMFS 2018).

TABLE 6—MODELED RADIAL DISTANCES TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS

Hearing group	SEL cumulative PTS threshold (dB) [1]	SEL cumulative PTS distance (m) [1]	Pk PTS threshold (dB) [1]	Pk PTS distance (m) [1]
Low-frequency cetaceans	183	25.4	219	6.69
Mid-frequency cetaceans	185	0.0	230	1.50
High-frequency cetaceans	155	0.0	202	47.02
Phocid pinnipeds	185	0.3	218	7.53
Otariid pinnpeds	203	0.0	232	0.92

[1] Cumulative sound exposure level for PTS (SEL_{cum}PTS) or Peak (SPLflat) resulting in Level A harassment (*i.e.,* injury). Based on 2018 NMFS Acoustic Technical Guidance (NMFS 2018).

Predicted distances to Level A harassment isopleths, which vary based on marine mammal hearing groups, were calculated based on modeling performed by L–DEO using the Nucleus software program and the NMFS User Spreadsheet, described below. The acoustic thresholds for impulsive sounds (*e.g.,* airguns) contained in the Technical Guidance were presented as dual metric acoustic thresholds using both SEL_{cum} and peak sound pressure metrics (NMFS 2016a). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group. In recognition of the fact that the requirement to calculate Level A harassment ensonified areas could be more technically challenging to predict due to the duration component and the use of weighting functions in the new SEL_{cum} thresholds, NMFS developed an optional User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to facilitate the estimation of take numbers.

The SEL_{cum} for the two-GI airgun array is derived from calculating the modified farfield signature. The farfield signature is often used as a theoretical representation of the source level. To compute the farfield signature, the source level is estimated at a large distance (right) below the array (*e.g.,* 9 km), and this level is back projected mathematically to a notional distance of 1 m from the array's geometrical center. However, it has been recognized that the source level from the theoretical farfield signature is never physically achieved at the source when the source is an array of multiple airguns separated in space (Tolstoy *et al.,* 2009). Near the source (at short ranges, distances <1 km), the pulses of sound pressure from each individual airgun in the source array do not stack constructively as they do for the theoretical farfield signature. The pulses from the different airguns spread out in time such that the source levels observed or modeled are the result of the summation of pulses from a few airguns, not the full array (Tolstoy *et al.,* 2009). At larger distances, away from the source array center, sound pressure of all the airguns in the array stack coherently, but not within one time sample, resulting in smaller source levels (a few dB) than the source level derived from the farfield signature. Because the farfield signature does not take into account the interactions of the two airguns that occur near the source center and is calculated as a point source (single airgun), the modified farfield signature is a more appropriate measure of the sound source level for large arrays. For this smaller array, the modified farfield changes will be correspondingly smaller as well, but this method is used for consistency across all array sizes.

The Level B harassment estimates are based on a consideration of the number of marine mammals that could be within the area around the operating airgun array where received levels of sound ≥160 dB re 1 μParms are predicted to occur (see Table 1). The estimated numbers are based on the densities (numbers per unit area) of marine mammals expected to occur in the area in the absence of seismic surveys. To the extent that marine mammals tend to move away from seismic sources before the sound level reaches the criterion level and tend not to approach an operating airgun array, these estimates likely overestimate the

numbers actually exposed to the specified level of sound.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

For the proposed survey area, NSF provided density data for marine mammal species that might be encountered in the project area. NMFS concurred that these data are the best available. Sightings data from the 2002–2003 (IWC–SOWER) Circumpolar Cruise, Area V (Ensor *et al.* 2003) were used to estimate densities for four mysticete (*i.e.,* humpback whale, Antarctic minke whale, fin whale, and blue whale) and six odontocete species (*i.e.,* sperm whale, southern bottlenose whale, strap-toothed beaked whale, killer whale, long-finned pilot whale and hourglass dolphin). Densities for sei and Arnoux's beaked whales were based on those reported in the Naval Marine Species Density Database (NMSDD) (Department of Navy 2012). NMFS finds NMSDD a reasonable representation of the lower likelihood of encountering these species, as evidenced by previous monitoring reports from projects in the same or similar area (85 FR 5619; January 31, 2020 & 0648–XD705;January 29, 2015) and primary literature on whale species density distribution in the Antarctic (Cetacean Population Studies Vol.2, 2020). Densities of pinnipeds were estimated using best available data (Waterhouse 2001; Pinkerton and Bradford-Grieve 2010) and dividing the estimated population of pinnipeds (number of animals) by the area of the Ross Sea (300,000 km^2). Estimated densities used and Level B harassment ensonified areas to inform take estimates are presented in Table 7.

TABLE 7—MARINE MAMMAL DENSITIES AND TOTAL ENSONIFIED AREA OF ACTIVITIES IN THE PROPOSED SURVEY AREA

Species	Estimated density (#/km^2)	Ross bank level B ensonified area (km^2)	Drygalski tough level B ensonified area (km^2)	Icebreaking level B ensonified area (km^2)
Fin whale	0.0306570	.....	.....	.....
Blue whale	0.0065132	.....	.....	.....
Sei whale	0.0046340	.....	.....	.....
Antarctic minke whale	0.0845595	.....	.....	.....
Humpback whale	0.0321169	.....	.....	.....
Sperm whale	0.0098821	.....	.....	.....
Southern bottlenose whale	0.0117912	.....	.....	.....
Arnoux's beaked whale	0.0134420	.....	.....	.....
Strap-toothed beaked whale	0.0044919	5,272	4,942	8,278
Killer whale	0.0208872	.....	.....	.....
Long-finned pilot whale	0.0399777	.....	.....	.....
Hourglass dolphin	0.0189782	.....	.....	.....
Crabeater seal	0.6800000	.....	.....	.....
Leopard seal	0.0266700	.....	.....	.....
Ross seal	0.0166700	.....	.....	.....
Weddell seal	0.1066700	.....	.....	.....
Southern elephant seal	0.0001300	.....	.....	.....

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

Seismic Surveys

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in Level B harassment, the radial distance from the airgun array to the predicted isopleth corresponding to the Level B harassment threshold is calculated, as described above. The radial distance is then used to calculate the area around the airgun array predicted to be ensonified to the sound level that exceed the Level B harassment threshold. The area estimated to be ensonified in a single day of the survey is then calculated (Table 8), based on the area predicted to be ensonified around the array and the estimated trackline distance traveled per day. The daily ensonified area was then multiplied by the number of estimated seismic acquisition days –9.6 days for the Ross Bay survey and 9 days for the Drygalski Trough survey. The product is then multiplied by 1.25 to account for the additional 25 percent contingency, as described above. This results in an estimate of the total area (km^2) expected to be ensonified to the Level B harassment threshold.

TABLE 8—AREA (KM^2) TO BE ENSONIFIED TO THE LEVEL B HARASSMENT THRESHOLD

Survey area	Distance/day (km)	Threshold distance (km)	Daily ensonified area with endcap (km^2)	Number of survey days	Plus 25% (contingency)	Total ensonified area (km^2)
Ross Bank	200	1.089	439	9.6	12	5,272
Drygaiski Trough	200	1.089	439	9	11.25	4,942

Based on the small Level A harassment isopleths (as shown in Table 6) and in consideration of the proposed mitigation measures (see Proposed Mitigation section below), take by Level A harassment is not expected to occur and is not proposed for authorization.

The marine mammals predicted to occur within the respective areas, based on estimated densities (Table 7), are assumed to be incidentally taken. Estimated take, and percentages of the stocks estimated to be taken, for the proposed survey are shown in Table 10.

Icebreaking

Applying the maximum estimated amount of icebreaking expected by NSF, *i.e.,* 500 km, we calculate the total ensonified area of icebreaking (Table 9). Estimates of exposures assume that there would be approximately 2 days of icebreaking activities; the calculated takes have been increased by 25 percent (2.75 days).

TABLE 9—ENSONIFIED AREA FOR ICEBREAKING ACTIVITIES

Criteria	Distance/day (km)	Threshold distance (km)	Daily ensonified area with endcap (km^2)	Number of survey days	Plus 25% (contingency)	Total ensonified area (km^2)
120 dB	223	6,456	3,010	2.2	2.75	8,278

Estimated take from icebreaking for the proposed survey are shown in Table 10. As most cetaceans do not occur in pack ice, the estimates of the numbers of marine mammals potentially exposed to sounds greater than the Level B harassment threshold (120 dB re 1 µPa rms) are precautionary and probably overestimate the actual numbers of marine mammals that could be involved. No takes by Level A harassment are expected or proposed for authorization. The estimated number of takes for pinnipeds accounts for both seals that may be in the water and those hauled out on ice surfaces. Few cetaceans are expected to be seen during icebreaking activities, although some could occur along the ice margin.

TABLE 10—TOTAL MARINE MAMMAL TAKE ESTIMATED FOR THE PROPOSED SURVEY IN THE ROSS SEA

Species	Level B take		Total take proposed for authorization	Population abundance	Percent of population
	All seismic	Icebreaking			
Fin whale	313	254	567	38,200	1.48
Blue whale	67	54	120	1,700	7.09
Sei whale	47	38	86	10,000	0.86
Antarctic minke whale	864	700	1,564	515,000	0.3
Humpback whale	328	266	594	42,000	1.41
Sperm whale	101	82	183	12,069	1.51
Southern bottlenose whale	120	98	218	599,300	0.04
Arnoux's beaked whale	137	111	249	599,300	0.04
Strap-toothed beaked whale	46	37	83	599,300	0.01
Killer whale	213	173	386	25,000	1.55
Long-finned pilot whale	408	331	739	200,000	0.37
Hourglass dolphin	194	157	351	144,300	0.24
Crabeater seal	6,946	5,629	12,575	1,700,000	1
Leopard seal	272	221	493	220,000	0.22
Ross seal	170	138	308	250,000	0.12
Weddell seal	1,090	883	1,973	1,000,000	0.2
Southern elephant seal	2	1	3	750,000	<0.01

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) the manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation measures that would be adopted during the planned survey include, but are not limited to: (1)

Vessel speed or course alteration, provided that doing so would not compromise operation safety requirements. (2) GI-airgun shut down within exclusion zones (EZ)s, and (3) ramp-up procedures.

Vessel-Visual Based Mitigation Monitoring

Visual monitoring requires the use of trained observers (herein referred to as visual protected species observers (PSOs)) to scan the ocean surface visually for the presence of marine mammals. The area to be scanned visually includes primarily the exclusion zone, within which observation of certain marine mammals requires shutdown of the acoustic source, but also the buffer zone. The buffer zone means an area beyond the exclusion zone to be monitored for the presence of marine mammals that may enter the exclusion zone. During pre-start clearance (*i.e.,* before ramp-up begins), the buffer zone also acts as an extension of the exclusion zone in that observations of marine mammals within the buffer zone would also prevent airgun operations from beginning (*i.e.,* ramp-up). The buffer zone encompasses the area at and below the sea surface from the edge of the 100 m exclusion zone measured from the edges of the airgun array. Visual monitoring of the exclusion zone and adjacent waters is intended to establish and, when visual conditions allow, maintain zones around the sound source that are clear of marine mammals, thereby reducing or eliminating the potential for injury and minimizing the potential for more severe behavioral reactions for animals occurring closer to the vessel. Visual monitoring of the buffer zone is intended to (1) provide additional protection to naïve marine mammals that may be in the area during pre-clearance, and (2) during airgun use, aid in establishing and maintaining the exclusion zone by altering the visual observer and crew of marine mammals that are outside of, but may approach and enter, the exclusion zone.

NSF must use independent, dedicated, trained visual PSOs, meaning that the PSOs must be employed by a third-party observer provider, must not have tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements, and must have successfully completed an approved PSO training course. PSO resumes shall be provided to NMFS for approval.

At least one visual PSO must have a minimum of 90 days at-sea experience working in that role during a shallow penetration or low-energy survey, with no more than 18 months elapsed since the conclusion of the at-sea experience. One PSO with such experience shall be designated as the lead for the entire protected species observation team. The lead PSO shall serve as primary point of contact for the vessel operator and ensure all PSO requirements per the IHA are met. To the maximum extent practicable, the experienced PSOs should be scheduled to be on duty with those PSOs with the appropriate training but who have not yet gained relevant experience.

During survey operations (*e.g.,* any day on which use of the acoustic source is planned to occur, and whenever the acoustic source is in the water, whether activated or not), a minimum of two PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and 30 minutes prior to and during ramp-up of the airgun array. Visual monitoring of the exclusion and buffer zones must begin no less than 30 minutes prior to ramp-up and must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. Visual PSOs must coordinate to ensure 360 degree visual coverage around the vessel from the most appropriate observation posts, and must conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner.

PSOs shall establish and monitor the exclusion and buffer zones. These zones shall be based upon the radial distance from the edges of the acoustic source (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source (*i.e.,* anytime airguns are active, including ramp-up) shall be communicated to the operator to prepare for the potential shutdown of the acoustic source.

During use of the airgun, detections of marine mammals within the buffer zone (but outside the exclusion zone) should be communicated to the operator to prepare for the potential shutdown of the acoustic source. Visual PSOs will immediately communicate all observations to the on duty acoustic PSO(s), including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination. Any observations of marine mammals by crew members shall be relayed to the PSO team. During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), visual PSOs shall conduct observations when the acoustic source is not operating for comparison of sightings rates and behavior with and without use of the acoustic source and between acquisition periods, to the maximum extent practicable.

Visual PSOs may be on watch for a maximum of four consecutive hours followed by a break of at least one hour between watches and may conduct a maximum of 12 hours of observation per 24-hour period.

Exclusion Zone and Buffer Zone

An exclusion zone (EZ) is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce the potential for certain outcome, *e.g.,* auditory injury, disruption of critical behaviors. The PSOs would establish a minimum EZ with a 100 m radius with an additional 100 m buffer zone (total of 200 m). The 200m zone would be based on radial distance from the edge of the airgun array (rather than being based on the center of the array or around the vessel itself). With certain exceptions (described below), if a marine mammal appears within or enters this zone, the acoustic source would be shut down.

The 100 m EZ, with additional 100 m buffer zone, is intended to be precautionary in the sense that it would be expected to contain sound exceeding the injury criteria for all cetacean hearing groups, (based on the dual criteria of SEL_{cum} and peak SPL), while also providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. Additionally, a 100 m EZ is expected to minimize the likelihood that marine mammals will be exposed to levels likely to result in more severe behavioral responses. Although significantly greater distances may be observed from an elevated platform under good conditions, we believe that 100 m is regularly attainable for PSOs using the naked eye during typical conditions.

An extended 500 m exclusion zone must be established for beaked whales, large whales with a calf, and an aggregation of whales during all survey effort. No buffer zone is required.

Pre-Clearance and Ramp-Up

Ramp-up (sometimes referred to as ''soft start'') is the gradual and systematic increase of emitted sound levels from an airgun array. Ramp-up would begin with one GI airgun 45 cu in first being activated, followed by the second after 5 minutes. The intent of pre-clearance observation (30 minutes)

is to ensure no marine mammals are observed within the buffer zone prior to the beginning of ramp-up. During pre-clearance is the only time observations of marine mammals in the buffer zone would prevent operations (*i.e.,* the beginning of ramp-up). The intent of ramp-up is to warn protected species of pending seismic operations and to allow sufficient time for those animals to leave the immediate vicinity. A ramp-up procedure, involving a stepwise increase in the number of airguns are activated and the full volume is achieve, is required at all times as part of the activation of the acoustic source. All operators must adhere to the following pre-clearance and ramp-up requirements:

(1) The operator must notify a designated PSO of the planned start of ramp-up as agreed upon with the lead PSO; the notification time should not be less than 60 minutes prior to the planned ramp-up in order to allow PSOs time to monitor the exclusion and buffer zones for 30 minutes prior to the initiation of ramp-up (pre-clearance);

- Ramp-ups shall be scheduled so as to minimize the time spent with the source activated prior to reaching the designated run-in;
- One of the PSOs conducting pre-clearance observations must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed;
- Ramp-up may not be initiated if any marine mammal is within the applicable exclusion or buffer zone. If a marine mammal is observed within the applicable exclusion zone or the buffer zone during the 30 minutes pre-clearance period, ramp-up may not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (15 minutes for small odontocetes and pinnipeds, and 30 minutes for Mysticetes and all other odontocetes, including sperm whales and beaked whales);
- PSOs must monitor the exclusion and buffer zones during ramp-up, and ramp-up must cease and the source must be shut down upon detection of a marine mammal within the applicable exclusion zone. Once ramp-up has begun, detections of marine mammals within the buffer zone do not require shutdown, but such observation shall be communicated to the operator to prepare for the potential shutdown.

(2) If the acoustic source is shut down for brief periods (*i.e.,* less than 30 minutes) for reasons other than that described for shutdown (*e.g.,* mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant observation and no detections of marine mammals have occurred within the applicable exclusion zone. For any longer shutdown, pre-start clearance observation and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required, but if the shutdown period was brief and constant observation was maintained, pre-start clearance watch is not required.

- Testing of the acoustic source involving all elements requires ramp-up. Testing limited to individual source elements or strings does not require ramp-up but does require pre-start clearance watch.

Shutdown Procedures

The shutdown of an airgun array requires the immediate de-activation of all individual airgun elements of the array. Any PSO on duty will have the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable exclusion zone. The operator must also establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. When both visual and acoustic PSOs are on duty, all detections will be immediately communicated to the remainder of the on-duty PSO team for potential verification of visual observations by the acoustic PSO or of acoustic detections by visual PSOs. When the airgun array is active (*i.e.,* anytime one or more airguns is active, including during ramp-up) and (1) a marine mammal appears within or enters the applicable exclusion zone and/or (2) a marine mammal (other than delphinids, see below) is detected acoustically and localized within the applicable exclusion zone, the acoustic source will be shut down. When shutdown is called for by a PSO, the acoustic source will be immediately deactivated and any dispute resolved only following deactivation.

Following a shutdown, airgun activity would not resume until the marine mammal has cleared the EZ. The animal would be considered to have cleared the EZ if it is visually observed to have departed the EZ, or it has not been seen within the EZ for 15 minutes in the case of small odontocetes and pinnipeds, and 30 minutes for Mysticetes and all other odontocetes, including sperm and beaked whales, with no further observation of the marine mammal(s).

Upon implementation of shutdown, the source may be reactivated after the marine mammal(s) has been observed exiting the applicable exclusion zone (*i.e.,* animal is not required to fully exit the buffer zone where applicable) or following a clearance period (15 minutes for small odontocetes and pinnipeds, and 30 minutes for mysticetes and all other odontocetes, including sperm whales, beaked whales, pilot whales, killer whales, and Risso's dolphin) with no further observation of the marine mammal(s).

NSF must implement shutdown if a marine mammal species for which take was not authorized, or a species for which authorization was granted but the takes have been met, approaches the Level B harassment zones.

Vessel Strike Avoidance Measures

These measures apply to all vessels associated with the planned survey activity; however, we note that these requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply. These measures include the following:

(1) Vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A single marine mammal at the surface may indicate the presence of submerged animals in the vicinity of the vessel; therefore, precautionary measures should be exercised when an animal is observed. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel (specific distances detailed below), to ensure the potential for strike is minimized. Visual observers monitoring the vessel strike avoidance zone can be either third-party observers or crew members, but crew members responsible for these duties must be provided sufficient training to distinguish marine mammals from other phenomena and broadly to identify a marine mammal to broad taxonomic group (*i.e.,* as a large whale or other marine mammal);

(2) Vessel speeds must be reduced to 10 kn or less when mother/calf pairs, pods, or large assemblages of any marine mammal are observed near a vessel;

(3) All vessels must maintain a minimum separation distance of 100 m from large whales (*i.e.,* sperm whales and all mysticetes);

(4) All vessels must attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an exception made for those animals that approach the vessel; and

(5) When marine mammals are sighted while a vessel is underway, the vessel should take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If marine mammals are sighted within the relevant separation distance, the vessel should reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This recommendation does not apply to any vessel towing gear.

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

(1) Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density).

(2) Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas).

(3) Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors.

(4) How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks.

(5) Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat).

(6) Mitigation and monitoring effectiveness.

Vessel-Based Visual Monitoring

As described above, PSO observations would take place during daytime airgun operations. During seismic operations, at least three visual PSO would be based aboard the *Palmer,* with a minimum of one on duty at all times during daylight hours. NMFS' typical requirements for surveys of this type include a minimum of two PSOs on duty at all times during daylight hours. However, NSF stated in communications with NMFS that the requirement is not practicable in this circumstance due to the remote location of the proposed survey and associated logistical issues, including limited capacity to fly PSOs into and out of McMurdo Station in Antarctica and limited berth space on the *Palmer,* and requested an exception to the requirement. NMFS agrees that, in this circumstance, the requirement to have a minimum of two PSOs on duty during all daylight hours would be impracticable and, therefore, proposes that a minimum of one PSO be on duty. NSF must employ two PSOs on duty during all daylight hours to the maximum extent practicable. NSF Monitoring shall be conducted in accordance with the following requirements:

(1) PSOs shall be independent, dedicated and trained and must be employed by a third-party observer provider;

(2) PSOs shall have no tasks other than to conduct visual observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements (including brief alerts regarding maritime hazards);

(3) PSOs shall have successfully completed an approved PSO training course appropriate for their designated task (visual or acoustic);

(4) NMFS must review and approve PSO resumes accompanied by a relevant training course information packet that includes the name and qualifications (*i.e.,* experience, training completed, or educational background) of the instructor(s), the course outline or syllabus, and course reference material as well as a document stating successful completion of the course;

(5) NMFS shall have one week to approve PSOs from the time that the necessary information is submitted, after which PSOs meeting the minimum requirements shall automatically be considered approved;

(6) PSOs must successfully complete relevant training, including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program;

(7) PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics; and

(8) The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Requests shall be granted or denied (with justification) by NMFS within one week of receipt of submitted information. Alternate experience that may be considered includes, but is not limited to

- secondary education and/or experience comparable to PSO duties;
- previous work experience conducting academic, commercial, or government-sponsored protected species surveys; or
- previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

PSOs must use standardized data collection forms, whether hard copy or electronic. PSOs must record detailed information about any implementation of mitigation requirements, including the distance of animals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up

of the acoustic source. If required mitigation was not implemented, PSOs should record a description of the circumstances. At a minimum, the following information must be recorded:

- Vessel name and call sign;
- PSO names and affiliations;
- Date and participants of PSO briefings (as discussed in General Requirement);
- Dates of departure and return to port with port name;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort began and ended and vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions changed significantly), including BSS and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;
- Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions changed (*e.g.,* vessel traffic, equipment malfunctions); and
- Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in the array, tow depth of the array, and any other notes of significance (*i.e.,* pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, *etc.*).

The following information should be recorded upon visual observation of any marine mammal:

- Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Vessel location at time of sighting;
- Water depth;
- Direction of vessel's travel (compass direction);
- Direction of animal's travel relative to the vessel;
- Pace of the animal;
- Estimated distance to the animal and its heading relative to vessel at initial sighting;
- Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and the composition of the group if there is a mix of species;
- Estimated number of animals (high/low/best);
- Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, *etc.*);
- Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
- Animal's closest point of approach (CPA) and/or closest distance from any element of the acoustic source;
- Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and
- Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up) and time and location of the action.

Reporting

NSF must submit a draft comprehensive report to NMFS on all activities and monitoring results within 90 days of the completion of the survey or expiration of the IHA, whichever comes sooner. A final report must be submitted within 30 days following resolution of any comments on the draft report. The report would describe the operations that were conducted and sightings of marine mammals near the operations. The report would provide full documentation of methods, results, and interpretation pertaining to all monitoring. The 90-day report would summarize the dates and locations of seismic operations, and all marine mammal sightings (dates, times, locations, activities, associated seismic survey activities). The report would also include estimates of the number and nature of exposures that occurred above the harassment threshold based on PSO observations and including an estimate of those that were not detected, in consideration of both the characteristics and behaviors of the species of marine mammals that affect detectability, as well as the environmental factors that affect detectability.

The draft report shall also include geo-referenced time-stamped vessel tracklines for all time periods during which airguns were operating. Tracklines should include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off, or when they changed from full array to single gun or vice versa). Geographic Information System (GIS) files shall be provided in Environmental Systems Research Institute (ESRI) shapefile format and include the Coordinated Universal Time (UTC) date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates shall be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available to NMFS. The report must summarize the information submitted in interim monthly reports as well as additional data collected as described above and in the IHA. A final report must be submitted within 30 days following resolution of any comments on the draft report.

Reporting Injured or Dead Marine Mammals

Discovery of injured or dead marine mammals—In the event that personnel involved in survey activities covered by the authorization discover an injured or dead marine mammal, the NSF shall report the incident to the Office of Protected Resources (OPR), NMFS as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, L–DEO shall report the incident to Office of Protected Resources (OPR), NMFS and to the NMFS West Coast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measure were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea

state, cloud cover, visibility) immediately preceding the strike;

- Species identification (if known) or description of the animal(s) involved;
- Estimated size and length of the animal that was struck;
- Description of the behavior of the animal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals present immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all the species listed in Table 2 given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar, except where a species- or stock-specific discussion is warranted. NMFS does not anticipate that serious injury or mortality would occur as a result from low-energy survey, even in the absence of mitigation, and no serious injury or mortality is proposed to be authorized. As discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, non-auditory physical effects and vessel strike are not expected to occur. NMFS expects that all potential take would be in the form of Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity was occurring), responses that are considered to be of low severity, and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007, 2021). These low-level impacts of behavioral harassment are not likely to impact the overall fitness of any individual or lead to population level effects of any species. As described above, Level A harassment is not expected to occur given the estimated small size of the Level A harassment zones.

In addition to being temporary, the maximum expected Level B harassment zone around the survey vessel is 1,089 m (and as much a 6,456 m for icebreaking activities). Therefore, the ensonified area surrounding the vessel is relatively small compared to the overall distribution of animals in the area and their use of the habitat. Feeding behavior is not likely to be significantly impacted as prey species are mobile and are broadly distributed throughout the survey area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the short duration (19 days) and temporary nature of the disturbance and the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

NMFS does not anticipate that serious injury or mortality would occur as a result of NSF's proposed seismic survey, even in the absence of proposed mitigation. Thus, the proposed authorization does not authorize any serious injury or mortality. As discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, non-auditory physical effects, stranding, and vessel strike are not expected to occur.

No takes by Level A harassment are proposed to be authorized. The 100-m EZ encompasses the Level A harassment isopleths for all marine mammal hearing groups, and is expected to prevent animals from being exposed to sound levels that would cause PTS. Also, as described above, we expect that marine mammals would be likely to move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice of the RVIB *Palmer's* approach due to the vessel's relatively low speed when conducting seismic survey. We expect that any instances of take would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007).

Potential impacts to marine mammal habitat were discussed previously in this document (see Potential Effects of Specified Activities on Marine Mammals and their Habitat). Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. Feeding behavior is not likely to be significantly impacted, as marine mammals appear to be less likely to exhibit behavioral reactions or avoidance responses while engaged in feeding activities (Richardson *et al.,* 1995). Prey species are mobile and are broadly distributed throughout the project area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, and the lack of important or unique marine mammal habitat, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. In addition, there are no feeding, mating or calving areas known to be biologically important to marine mammals within the proposed project area.

As explained above in the Description of Marine Mammals in the Area of Specified Activities section, marine mammals in the survey area are not assigned to NMFS stocks. Therefore, we rely on the best available information on the abundance estimates for the species of marine mammals that could be taken.

The activity is expected to impact a very small percentage of all marine mammal populations that would be affected by NSF's proposed survey (approximately three percent or less each for all marine mammal populations where abundance estimates exist). Additionally, the acoustic ''footprint'' of the proposed survey would be very small relative to the ranges of all marine mammal species that would potentially be affected. Sound levels would increase in the marine environment in a relatively small area surrounding the vessel compared to the range of the marine mammals within the proposed survey area. The seismic array would be active 24 hours per day throughout the duration of the proposed survey. However, the very brief overall duration of the proposed survey (19 days) would further limit potential impacts that may occur as a result of the proposed activity.

The proposed mitigation measures are expected to reduce the number and/or severity of takes by allowing for detection of marine mammals in the vicinity of the vessel by visual observers, and by minimizing the severity of any potential exposures via ramp-ups and shutdowns of the airgun array.

Of the marine mammal species that are likely to occur in the project area, the following species are listed as endangered under the ESA: blue, fin, sei, and sperm whales. We are proposing to authorize very small numbers of takes for these species (Table 9), relative to their population sizes (again, for species where population abundance estimates exist), therefore we do not expect population-level impacts to any of these species. The other marine mammal species that may be taken by harassment during NSF's seismic survey are not listed as threatened or endangered under the ESA. There is no designated critical habitat for any ESA-listed marine mammals within the project area.

NMFS concludes that exposures of marine mammals due to NSF's proposed seismic survey would result in only short-term (temporary and short in duration) effects to individuals exposed. Marine mammals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success are not expected. NMFS does not anticipate the proposed take estimates to impact annual rates of recruitment or survival.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

(1) No mortality, serious injury or Level A harassment is anticipated or proposed to be authorized;

(2) The anticipated impacts of the proposed activity on marine mammals would primarily be temporary behavioral changes of small percentages of the affected species due to avoidance of the area around the survey vessel. The relatively short duration of the proposed survey (19 days) would further limit the potential impacts of any temporary behavioral changes that would occur;

(3) The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the proposed survey to avoid exposure to sounds from the activity;

(4) The potential adverse effects of the proposed survey on fish or invertebrate species that serve as prey species for marine mammals would be temporary and spatially limited; and

(5) The proposed mitigation measures, including visual monitoring, ramp-ups, and shutdowns, are expected to minimize potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity would have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is below one third of the estimated stock abundance for all species (in fact, take of individuals is less than ten percent of the abundance of the affected stocks, see Table 10). This is likely a conservative estimate because we assume all takes are of different individual animals, which is likely not the case. Some individuals may be encountered multiple times in a day, but PSOs would count them as separate individuals if they cannot be identified.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population sizes of the affected species.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal species or stocks implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

We propose to authorize take of blue, fin, sei, and sperm whales, which are listed under the ESA, and have requested initiation of Section 7 consultation for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to NSF for conducting seismic survey and icebreaking in the Ross Sea, in January through February 2023, provided the previously mentioned mitigation, monitoring, and reporting

requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed low-energy marine geophysical survey and icebreaking activity in the Ross Sea. We also request at this time comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal.

On a case-by-case basis, NMFS may issue a one-year IHA renewal with an additional 15 days for public comments when (1) another year of identical or nearly identical activities as described in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section of this notice is planned or (2) the activities as described in the Specified Activities section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

(1) A request for renewal is received no later than 60 days prior to expiration of the current IHA.

(2) The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested Renewal 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 because only a subset of the initially analyzed activities remain to be completed under the Renewal).
- 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.
- 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.

Dated: September 22, 2022.

Kimberly Damon-Randall,

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

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Part IV

Small Business Administration

13 CFR Part 121
Small Business Size Standards: Adoption of 2022 North American Industry Classification System for Size Standards; Final Rule

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AH89

Small Business Size Standards: Adoption of 2022 North American Industry Classification System for Size Standards

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (''SBA'' or ''Agency'') amends its small business size regulations to incorporate the U.S. Office of Management and Budget's (OMB) North American Industry Classification System (NAICS) revision for 2022, identified as NAICS 2022, into its table of small business size standards. The NAICS 2022 revision created 111 new industries by reclassifying, combining, or splitting 156 NAICS 2017 industries or their parts. SBA's size standards for these 111 new industries under NAICS 2022 have resulted in an increase to the size standards for 22 industries and 29 parts of two industries under NAICS 2017, a decrease to size standards for seven industries and 53 parts of two industries, a change in the size standard measure from average annual receipts to number of employees for one industry, a change in the size standard measure from number of employees to average annual receipts for a part of one industry, and no change in size standards for 117 industries and 19 parts of seven industries.

DATES: This rule is effective October 1, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Khem R. Sharma, Chief, Office of Size Standards, (202) 205–6618 or *sizestandards@sba.gov.* This phone number can also be reached by individuals who are deaf or hard of hearing, or who have speech disabilities, through the Federal Communications Commission's TTY-Based Telecommunications Relay Service teletype service at 711.

SUPPLEMENTARY INFORMATION: Effective October 1, 2000, the U.S. Small Business Administration (SBA) adopted North American Industry Classification System (NAICS) 1997 industry definitions as a basis for defining industries for its table of small business size standards, replacing the 1987 Standard Industrial Classification (SIC) (65 FR 30836 (May 15, 2000)). Since then, the Office of Management and Budget (OMB) has issued five revisions to NAICS. SBA's table of size standards adopted the OMB's first revision, NAICS 2002, effective October 1, 2002 (67 FR 52597 (August 13, 2002)); the second revision, NAICS 2007, effective October 1, 2007 (72 FR 49639 (August 29, 2007)); the third revision, NAICS 2012, effective October 1, 2012 (77 FR 49991 (August 20, 2012)); and fourth revision, NAICS 2017, effective October 1, 2017 (82 FR 44886 (September 27, 2017)).

On December 21, 2021, OMB published its fifth and latest revision to NAICS ''Notice of NAICS 2022 Final Decisions; Update of Statistical Policy Directive No. 8, North American Industry Classification System: Classification of Establishments; and Elimination of Statistical Policy Directive No. 9, Standard Industrial Classification of Enterprises'' (86 FR 72277). In the December 21, 2021, **Federal Register** notice, OMB accepted the Economic Classification Policy Committee's (ECPC) recommendations, as outlined in the July 2, 2021, **Federal Register** notice (86 FR 35350), for the 2022 revisions to NAICS, as well as the recommendations to update OMB Statistical Policy Directive No. 8, *North American Industry Classification System: Classification of Establishments* and to eliminate OMB Statistical Policy Directive No. 9, *Standard Industrial Classification of Enterprises.*

The OMB's notice stated that Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using NAICS 2022. Although SBA is not a statistical agency, it is adopting NAICS 2022 for its table of size standards, effective October 1, 2022.

As with the previous NAICS revisions, SBA is adopting the latest NAICS revision, identified as NAICS 2022, effective October 1, 2022 (*i.e.,* the beginning of the new fiscal year following the effective date of the OMB's release of the NAICS 2022 revision), for several reasons: (1) Federal Government contracting data and related statistics will be more consistent and comparable with past data for analyzing future small business activity if implementation of the revised table of size standards occurs at the beginning of a new fiscal year; (2) users of size standards, for instance, Federal prime contractors, who may use the size standards for developing their subcontracting plans, can have more consistent data to examine the past and future Federal contracting trends; and (3) small business size standards apply to most Federal agencies and their programs involving small businesses; with a time lag between the OMB's effective date and SBA's update of its size standards, agencies will have sufficient time to implement the changes and develop training tools, if necessary.

Changes in NAICS 2022

The NAICS 2022 revision created 111 new NAICS industries by splitting, merging, or modifying 6-digit codes or industry titles/definitions of 156 exiting industries under NAICS 2017 structure, of which nine industries were split to two or more NAICS 2022 industries. On July 5, 2022, SBA published proposed size standards for the new industries under NAICS 2022 (87 FR 40034). These changes are broken down by NAICS sector in Table 1, ''Modified Industries under NAICS 2017 and New Industries under NAICS 2022 by NAICS Sector.'' As can be seen in Table 1, Sector 44–45 (Retail Trade) accounts for the largest proportions of NAICS 2017 industries that have changed or been amended and of the new industries that have been created under NAICS 2022, followed by Sector 31–33 (Manufacturing), and Sector 51 (Information).

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Table 1
Modified Industries under NAICS 2017 and New Industries under NAICS 2022 by NAICS Sector

NAICS Sector	Existing NAICS 2017 Industries Changed		New NAICS 2022 Industries Created	
	Count	%	Count	%
Sector 21	13	8.3%	6	5.4%
Sector 31-33	33	21.2%	19	1.8%
Sector 42	4	2.6%	2	2.7%
Sector 44-45	62	39.7%	53	47.7%
Sector 51	20	12.8%	18	16.2%
Sector 52	12	7.7%	6	5.4%
Sector 81	7	4.5%	2	1.8%
Sectors 48-49, 54, 56 & 62	5	3.2%	5	4.5%
All Sectors	156	100.0%	111	100.0%

Of the 111 new industries under NAICS 2022, 79 (71% of the new industries) were created by merging two or more NAICS 2017 industries in their entirety, one or more of NAICS 2017 industries and part(s) of one or more NAICS 2017 industries, or parts of two or more NAICS 2017 industries. Altogether, 125 NAICS 2017 industries or their parts were involved in the creation of the 79 new industries. Of the remaining 32 new industries, OMB changed the 6-digit codes for 11 (10%) NAICS 2017 industries without changing their titles, amended the industry titles of 14 (13%) NAICS 2017 industries without changing their 6-digit codes, and created seven (6%) new industries by modifying the title, 6-digit code, or definition (or any combination thereof) of a single NAICS 2017 industry or part. These results are summarized in Table 2, ''Summary of NAICS 2022 Changes.''

Table 2
Summary of NAICS 2022 Changes

Types of new industries formed	Count	%
New industries formed by merging two or more NAICS 2017 industries or their parts[1]	79	71.2%
NAICS 2017 industries for which 6-digit codes have changed without changing their titles	11	9.9%
NAICS 2017 industries for which titles have changed without changing their 6-digit codes	14	12.6%
NAICS 2017 industries for which titles, 6-digit codes, or definitions have changed, mostly by splitting a single NAICS 2017 industry	7	6.3%
Total	111	100.0%

[1]Of the 79 NAICS 2022 new industries, 15 industries formed by merging two or more NAICS 2017 industries or their parts used the NAICS 2017 industry titles, of which 14 used different 6-digit codes and one used the same NAICS 2017 industry code.

Complete information on the relationship between NAICS 2017 and NAICS 2022 is available on the U.S. Bureau of the Census (Census Bureau) website at *https://www.census.gov/naics/*. The Census Bureau's website also provides detailed documentation on Federal notices involving the replacement of SIC with NAICS, and all subsequent NAICS updates and revisions, including both the July 2, 2021 and December 21, 2021, **Federal Register** notices regarding the NAICS 2022 revision.

Of the 79 new NAICS 2022 industries formed by merging existing NAICS 2017 industries or their parts, 33 or 42% were formed by merging one NAICS 2017 industry with parts of two other NAICS 2017 industries.[1] Likewise, 20 or 25% of new industries were formed by merging two NAICS 2017 industries, and 12 or 15% were formed by merging one NAICS 2017 industry with part of another industry. These results and the formation of the remaining 14 or 18% of new industries are summarized in Table 3, ''Formation of New Industries in NAICS 2022.''

Table 3
Formation of New Industries in NAICS 2022

	NAICS 2022 New Industries Formed by Merging NAICS 2017 Industries or Their Parts	
NAICS 2017 Industries or Their Parts	Count	%
One industry and parts of two industries	33	41.8%
Two industries	20	25.3%
One industry and part of one industry	12	15.2%
Three industries	4	5.1%
Two industries and parts of two industries	2	2.5%
One industry and parts of three industries	2	2.5%
Four industries	2	2.5%
Parts of three industries	1	1.3%
Parts of two industries	1	1.3%
Three industries and part of two industries	1	1.3%
Six industries and parts of two industries	1	1.3%
Total	79	100.0%

Table 4, ''NAICS 2017 Industries or Their Parts Matched to NAICS 2022 Industries,'' below, shows the detailed changes from NAICS 2017 to NAICS 2022.

[1] These 33 industries were in Sector 44–45 (Retail Trade). Specifically, NAICS 2017 industry 454110 (Electronic Shopping and Mail-Order Houses) was split to and distributed across 42 different retail trade industries, and similarly NAICS 454390 (Other Direct Selling Establishments) was split to and distributed across 39 different retail trade industries, which were in turn merged with 33 different Retail Trade industries.

Table 4
NAICS 2017 Industries or Their Parts Matched to NAICS 2022 Industries

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
212111	Bituminous Coal and Lignite Surface Mining	pt.	**212114**	Surface Coal Mining
212112	Bituminous Coal Underground Mining	pt.	**212115**	Underground Coal Mining
212113	Anthracite Mining - *anthracite surface mining*	pt.	**212114**	Surface Coal Mining
212113	Anthracite Mining - *anthracite underground mining*	pt.	**212115**	Underground Coal Mining
212221	Gold Ore Mining	pt.	**212220**	Gold Ore and Silver Ore Mining
212222	Silver Ore Mining	pt.	**212220**	Gold Ore and Silver Ore Mining
212291	Uranium-Radium-Vanadium Ore Mining	pt.	**212290**	Other Metal Ore Mining
212299	All Other Metal Ore Mining	pt.	**212290**	Other Metal Ore Mining
212324	Kaolin and Ball Clay Mining	pt.	**212323**	Kaolin, Clay, and Ceramic and Refractory Minerals Mining
212325	Clay and Ceramic and Refractory Minerals Mining	pt.	**212323**	Kaolin, Clay, and Ceramic and Refractory Minerals Mining
212391	Potash, Soda, and Borate Mineral Mining	pt.	**212390**	Other Nonmetallic Mineral Mining and Quarrying
212392	Phosphate Rock Mining	pt.	**212390**	Other Nonmetallic Mineral Mining and Quarrying
212393	Other Chemical and Fertilizer Mineral Mining	pt.	**212390**	Other Nonmetallic Mineral Mining and Quarrying
212399	All Other Nonmetallic Mineral Mining	pt.	**212390**	Other Nonmetallic Mineral Mining and Quarrying
311221	Wet Corn Milling	nt.	311221	Wet Corn Milling and Starch Manufacturing
315110	Hosiery and Sock Mills	pt.	**315120**	Apparel Knitting Mills
315190	Other Apparel Knitting Mills	pt.	**315120**	Apparel Knitting Mills
315220	Men's and Boys' Cut and Sew Apparel Manufacturing	pt.	**315250**	Cut and Sew Apparel Manufacturing (except Contractors)
315240	Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	pt.	**315250**	Cut and Sew Apparel Manufacturing (except Contractors)
315280	Other Cut and Sew Apparel Manufacturing	pt.	**315250**	Cut and Sew Apparel Manufacturing (except Contractors)

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
316992	Women's Handbag and Purse Manufacturing	pt.	**316990**	Other Leather and Allied Product Manufacturing
316998	All Other Leather Good and Allied Product Manufacturing	pt.	**316990**	Other Leather and Allied Product Manufacturing
321213	Engineered Wood Member (except Truss) Manufacturing	pt.	**321215**	Engineered Wood Member Manufacturing
321214	Truss Manufacturing	pt.	**321215**	Engineered Wood Member Manufacturing
322121	Paper (except Newsprint) Mills	pt.	**322120**	Paper Mills
322122	Newsprint Mills	pt.	**322120**	Paper Mills
325314	Fertilizer (Mixing Only) Manufacturing - *except compost manufacturing*	nt.	325314	Fertilizer (Mixing Only) Manufacturing
325314	Fertilizer (Mixing Only) Manufacturing - *compost manufacturing*	nct.	325315	Compost Manufacturing
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	nt.	325992	Photographic Film, Paper, Plate, Chemical, and Copy Toner Manufacturing
333244	Printing Machinery and Equipment Manufacturing	pt.	**333248**	All Other Industrial Machinery Manufacturing
333249	Other Industrial Machinery Manufacturing	pt.	**333248**	All Other Industrial Machinery Manufacturing
333314	Optical Instrument and Lens Manufacturing	pt.	**333310**	Commercial and Service Industry Machinery Manufacturing
333316	Photographic and Photocopying Equipment Manufacturing	pt.	**333310**	Commercial and Service Industry Machinery Manufacturing
333318	Other Commercial and Service Industry Machinery Manufacturing	pt.	**333310**	Commercial and Service Industry Machinery Manufacturing
333997	Scale and Balance Manufacturing	pt.	**333998**	All Other Miscellaneous General Purpose Machinery Manufacturing
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	pt.	**333998**	All Other Miscellaneous General Purpose Machinery Manufacturing
334613	Blank Magnetic and Optical Recording Media Manufacturing	pt.	**334610**	Manufacturing and Reproducing Magnetic and Optical Media
334614	Software and Other Prerecorded Compact Disc, Tape, and Record Reproducing	pt.	**334610**	Manufacturing and Reproducing Magnetic and Optical Media
335110	Electric Lamp Bulb and Part Manufacturing	pt.	**335139**	Electric Lamp Bulb and Other Lighting Equipment Manufacturing
335121	Residential Electric Lighting Fixture Manufacturing	nc.	335131	Residential Electric Lighting Fixture Manufacturing

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	nc.	335132	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing
335129	Other Lighting Equipment Manufacturing	pt.	**335139**	Electric Lamp Bulb and Other Lighting Equipment Manufacturing
335911	Storage Battery Manufacturing	pt.	**335910**	Battery Manufacturing
335912	Primary Battery Manufacturing	pt.	**335910**	Battery Manufacturing
336111	Automobile Manufacturing	pt.	**336110**	Automobile and Light Duty Motor Vehicle Manufacturing
336112	Light Truck and Utility Vehicle Manufacturing	pt.	**336110**	Automobile and Light Duty Motor Vehicle Manufacturing
337124	Metal Household Furniture Manufacturing	pt.	**337126**	Household Furniture (except Wood and Upholstered) Manufacturing
337125	Household Furniture (except Wood and Metal) Manufacturing	pt.	**337126**	Household Furniture (except Wood and Upholstered) Manufacturing
424320	Men's and Boys' Clothing and Furnishings Merchant Wholesalers	pt.	**424350**	Clothing and Clothing Accessories Merchant Wholesalers
424330	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers	pt.	**424350**	Clothing and Clothing Accessories Merchant Wholesalers
424940	Tobacco and Tobacco Product Merchant Wholesalers	nt.	424940	Tobacco Product and Electronic Cigarette Merchant Wholesalers
425110	Business to Business Electronic Markets	pt.	**425120**	Wholesale Trade Agents and Brokers
425120	Wholesale Trade Agents and Brokers	pt.	**425120**	Wholesale Trade Agents and Brokers
441228	Motorcycle, ATV, and All Other Motor Vehicle Dealers	pt.	**441227**	Motorcycle, ATV, and All Other Motor Vehicle Dealers
441310	Automotive Parts and Accessories Stores	pt.	**441330**	Automotive Parts and Accessories Retailers
441320	Tire Dealers	pt.	**441340**	Tire Dealers
442110	Furniture Stores	pt.	**449110**	Furniture Retailers
442210	Floor Covering Stores	pt.	**449121**	Floor Covering Retailers
442291	Window Treatment Stores	pt.	**449122**	Window Treatment Retailers
442299	All Other Home Furnishings Stores	pt.	**449129**	All Other Home Furnishings Retailers
443141	Household Appliance Stores	pt.	**449210**	Electronics and Appliance Retailers
443142	Electronics Stores	pt.	**449210**	Electronics and Appliance Retailers
444120	Paint and Wallpaper Stores	nt.	444120	Paint and Wallpaper Retailers
444130	Hardware Stores	pt.	**444140**	Hardware Retailers
444190	Other Building Material Dealers	pt.	**444180**	Other Building Material Dealers

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
444210	Outdoor Power Equipment Stores	pt.	**444230**	Outdoor Power Equipment Retailers
444220	Nursery, Garden Center, and Farm Supply Stores	pt.	**444240**	Nursery, Garden Center, and Farm Supply Retailers
445110	Supermarkets and Other Grocery (except Convenience) Stores	nt.	445110	Supermarkets and Other Grocery Retailers (except Convenience Retailers)
445120	Convenience Stores	pt.	**445131**	Convenience Retailers
445210	Meat Markets	pt.	**445240**	Meat Retailers
445220	Fish and Seafood Markets	pt.	**445250**	Fish and Seafood Retailers
445230	Fruit and Vegetable Markets	nt.	445230	Fruit and Vegetable Retailers
445291	Baked Goods Stores	nt.	445291	Baked Goods Retailers
445292	Confectionery and Nut Stores	nt.	445292	Confectionery and Nut Retailers
445299	All Other Specialty Food Stores	pt.	**445298**	All Other Specialty Food Retailers
445310	Beer, Wine, and Liquor Stores	pt.	**445320**	Beer, Wine, and Liquor Retailers
446110	Pharmacies and Drug Stores	pt.	**456110**	Pharmacies and Drug Retailers
446120	Cosmetics, Beauty Supplies, and Perfume Stores	pt.	**456120**	Cosmetics, Beauty Supplies, and Perfume Retailers
446130	Optical Goods Stores	pt.	**456130**	Optical Goods Retailers
446191	Food (Health) Supplement Stores	pt.	**456191**	Food (Health) Supplement Retailers
446199	All Other Health and Personal Care Stores	pt.	**456199**	All Other Health and Personal Care Retailers
447110	Gasoline Stations with Convenience Stores	nc.	457110	Gasoline Stations with Convenience Stores
447190	Other Gasoline Stations	nc.	457120	Other Gasoline Stations
448110	Men's Clothing Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448120	Women's Clothing Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448130	Children's and Infants' Clothing Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448140	Family Clothing Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448150	Clothing Accessories Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448190	Other Clothing Stores	pt.	**458110**	Clothing and Clothing Accessories Retailers
448210	Shoe Stores	pt.	**458210**	Shoe Retailers
448310	Jewelry Stores	pt.	**458310**	Jewelry Retailers
448320	Luggage and Leather Goods Stores	pt.	**458320**	Luggage and Leather Goods Retailers
451110	Sporting Goods Stores	pt.	**459110**	Sporting Goods Retailers
451120	Hobby, Toy, and Game Stores	pt.	**459120**	Hobby, Toy, and Game Retailers
451130	Sewing, Needlework, and Piece Goods Stores	pt.	**459130**	Sewing, Needlework, and Piece Goods Retailers

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
451140	Musical Instrument and Supplies Stores	pt.	**459140**	Musical Instrument and Supplies Retailers
451211	Book Stores	pt.	**459210**	Book Retailers and News Dealers
451212	News Dealers and Newsstands	pt.	**459210**	Book Retailers and News Dealers
452210	Department Stores	pt.	**455110**	Department Stores
452311	Warehouse Clubs and Supercenters	pt.	**455211**	Warehouse Clubs and Supercenters
452319	All Other General Merchandise Stores	pt.	**455219**	All Other General Merchandise Retailers
453110	Florists	pt.	**459310**	Florists
453210	Office Supplies and Stationery Stores	pt.	**459410**	Office Supplies and Stationery Retailers
453220	Gift, Novelty, and Souvenir Stores	pt.	**459420**	Gift, Novelty, and Souvenir Retailers
453310	Used Merchandise Stores	pt.	**459510**	Used Merchandise Retailers
453910	Pet and Pet Supplies Stores	pt.	**459910**	Pet and Pet Supplies Retailers
453920	Art Dealers	pt.	**459920**	Art Dealers
453930	Manufactured (Mobile) Home Dealers	nc.	459930	Manufactured (Mobile) Home Dealers
453991	Tobacco Stores	pt.	**459991**	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *general merchandise auction houses*	pt.	**455219**	All Other General Merchandise Retailers
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *electronic cigarette stores and marijuana stores, medical or recreational*	pt.	**459991**	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *except general merchandise auction houses, electronic cigarette stores, and marijuana stores, medical or recreational*	pt.	**459999**	All Other Miscellaneous Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**441227**	Motorcycle, ATV, and All Other Motor Vehicle Dealers
454110	Electronic Shopping and Mail-Order Houses	pt.	**441330**	Automotive Parts and Accessories Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**441340**	Tire Dealers
454110	Electronic Shopping and Mail-Order Houses	pt.	**444140**	Hardware Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**444180**	Other Building Material Dealers
454110	Electronic Shopping and Mail-Order Houses	pt.	**444230**	Outdoor Power Equipment Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**444240**	Nursery, Garden Center, and Farm Supply Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**445131**	Convenience Retailers

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
454110	Electronic Shopping and Mail-Order Houses	pt.	**445240**	Meat Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**445250**	Fish and Seafood Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**445298**	All Other Specialty Food Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**445320**	Beer, Wine, and Liquor Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**449110**	Furniture Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**449121**	Floor Covering Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**449122**	Window Treatment Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**449129**	All Other Home Furnishings Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**449210**	Electronics and Appliance Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**455110**	Department Stores
454110	Electronic Shopping and Mail-Order Houses	pt.	**455211**	Warehouse Clubs and Supercenters
454110	Electronic Shopping and Mail-Order Houses	pt.	**455219**	All Other General Merchandise Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**456110**	Pharmacies and Drug Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**456120**	Cosmetics, Beauty Supplies, and Perfume Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**456130**	Optical Goods Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**456191**	Food (Health) Supplement Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**456199**	All Other Health and Personal Care Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**458110**	Clothing and Clothing Accessories Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**458210**	Shoe Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**458310**	Jewelry Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**458320**	Luggage and Leather Goods Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459110**	Sporting Goods Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459120**	Hobby, Toy, and Game Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459130**	Sewing, Needlework, and Piece Goods Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459140**	Musical Instrument and Supplies Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459210**	Book Retailers and News Dealers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459310**	Florists
454110	Electronic Shopping and Mail-Order Houses	pt.	**459410**	Office Supplies and Stationery Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459420**	Gift, Novelty, and Souvenir Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459510**	Used Merchandise Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459910**	Pet and Pet Supplies Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459920**	Art Dealers

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
454110	Electronic Shopping and Mail-Order Houses	pt.	**459991**	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers
454110	Electronic Shopping and Mail-Order Houses	pt.	**459999**	All Other Miscellaneous Retailers
454210	Vending Machine Operators	nc.	445132	Vending Machine Operators
454310	Fuel Dealers	nc.	457210	Fuel Dealers
454390	Other Direct Selling Establishments	pt.	**441330**	Automotive Parts and Accessories Retailers
454390	Other Direct Selling Establishments	pt.	**441340**	Tire Dealers
454390	Other Direct Selling Establishments	pt.	**444140**	Hardware Retailers
454390	Other Direct Selling Establishments	pt.	**444180**	Other Building Material Dealers
454390	Other Direct Selling Establishments	pt.	**444230**	Outdoor Power Equipment Retailers
454390	Other Direct Selling Establishments	pt.	**444240**	Nursery, Garden Center, and Farm Supply Retailers
454390	Other Direct Selling Establishments	pt.	**445131**	Convenience Retailers
454390	Other Direct Selling Establishments	pt.	**445240**	Meat Retailers
454390	Other Direct Selling Establishments	pt.	**445250**	Fish and Seafood Retailers
454390	Other Direct Selling Establishments	pt.	**445298**	All Other Specialty Food Retailers
454390	Other Direct Selling Establishments	pt.	**445320**	Beer, Wine, and Liquor Retailers
454390	Other Direct Selling Establishments	pt.	**449110**	Furniture Retailers
454390	Other Direct Selling Establishments	pt.	**449121**	Floor Covering Retailers
454390	Other Direct Selling Establishments	pt.	**449122**	Window Treatment Retailers
454390	Other Direct Selling Establishments	pt.	**449129**	All Other Home Furnishings Retailers
454390	Other Direct Selling Establishments	pt.	**449210**	Electronics and Appliance Retailers
454390	Other Direct Selling Establishments	pt.	**455219**	All Other General Merchandise Retailers
454390	Other Direct Selling Establishments	pt.	**456110**	Pharmacies and Drug Retailers
454390	Other Direct Selling Establishments	pt.	**456120**	Cosmetics, Beauty Supplies, and Perfume Retailers
454390	Other Direct Selling Establishments	pt.	**456130**	Optical Goods Retailers
454390	Other Direct Selling Establishments	pt.	**456191**	Food (Health) Supplement Retailers
454390	Other Direct Selling Establishments	pt.	**456199**	All Other Health and Personal Care Retailers
454390	Other Direct Selling Establishments	pt.	**458110**	Clothing and Clothing Accessories Retailers
454390	Other Direct Selling Establishments	pt.	**458210**	Shoe Retailers
454390	Other Direct Selling Establishments	pt.	**458310**	Jewelry Retailers
454390	Other Direct Selling Establishments	pt.	**458320**	Luggage and Leather Goods Retailers
454390	Other Direct Selling Establishments	pt.	**459110**	Sporting Goods Retailers
454390	Other Direct Selling Establishments	pt.	**459120**	Hobby, Toy, and Game Retailers

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
454390	Other Direct Selling Establishments	pt.	**459130**	Sewing, Needlework, and Piece Goods Retailers
454390	Other Direct Selling Establishments	pt.	**459140**	Musical Instrument and Supplies Retailers
454390	Other Direct Selling Establishments	pt.	**459210**	Book Retailers and News Dealers
454390	Other Direct Selling Establishments	pt.	**459310**	Florists
454390	Other Direct Selling Establishments	pt.	**459410**	Office Supplies and Stationery Retailers
454390	Other Direct Selling Establishments	pt.	**459420**	Gift, Novelty, and Souvenir Retailers
454390	Other Direct Selling Establishments	pt.	**459510**	Used Merchandise Retailers
454390	Other Direct Selling Establishments	pt.	**459910**	Pet and Pet Supplies Retailers
454390	Other Direct Selling Establishments	pt.	**459920**	Art Dealers
454390	Other Direct Selling Establishments	pt.	**459991**	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers
454390	Other Direct Selling Establishments	pt.	**459999**	All Other Miscellaneous Retailers
485310	Taxi Service	nt.	485310	Taxi and Ridesharing Services
511110	Newspaper Publishers	pt.	**513110**	Newspaper Publishers
511120	Periodical Publishers	pt.	**513120**	Periodical Publishers
511130	Book Publishers	pt.	**513130**	Book Publishers
511140	Directory and Mailing List Publishers	pt.	**513140**	Directory and Mailing List Publishers
511191	Greeting Card Publishers	pt.	**513191**	Greeting Card Publishers
511199	All Other Publishers	pt.	**513199**	All Other Publishers
511210	Software Publishers	nc.	513210	Software Publishers
515111	Radio Networks	pt.	**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers
515112	Radio Stations	nct.	516110	Radio Broadcasting Stations
515120	Television Broadcasting - *television broadcasting stations*	nct.	516120	Television Broadcasting Stations
515120	Television Broadcasting - *television networks*	pt.	**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers
515210	Cable and Other Subscription Programming	pt.	**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers
517311	Wired Telecommunications Carriers	nc.	517111	Wired Telecommunications Carriers
517312	Wireless Telecommunications Carriers (except Satellite) - *except agents for wireless telecommunications carriers*	nct.	517112	Wireless Telecommunications Carriers (except Satellite)

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
517312	Wireless Telecommunications Carriers (except Satellite) - *agents for wireless telecommunications carriers*	pt.	**517122**	Agents for Wireless Telecommunications Services
517911	Telecommunications Resellers - *except agents for wireless telecommunications resellers*	nct.	517121	Telecommunications Resellers
517911	Telecommunications Resellers - *agents for wireless telecommunications resellers*	pt.	**517122**	Agents for Wireless Telecommunications Services
517919	All Other Telecommunications	nc.	517810	All Other Telecommunications
518210	Data Processing, Hosting, and Related Services	nt.	518210	Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services
519110	News Syndicates	pt.	**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers
519120	Libraries and Archives	nc.	519210	Libraries and Archives
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet newspaper publishers*	pt.	**513110**	Newspaper Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet periodical publishers*	pt.	**513120**	Periodical Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet book publishers*	pt.	**513130**	Book Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet directory and mailing list publishers*	pt.	**513140**	Directory and Mailing List Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet greeting card publishers*	pt.	**513191**	Greeting Card Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *all other Internet publishers*	pt.	**513199**	All Other Publishers
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet broadcasting*	pt.	**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers
519130	Internet Publishing and Broadcasting and Web Search Portals - *web search portals*	pt.	**519290**	Web Search Portals and All Other Information Services
519190	All Other Information Services	pt.	**519290**	Web Search Portals and All Other Information Services

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Status Code	NAICS 2022 Code	NAICS 2022 U.S. Industry Title
522120	Savings Institutions	pt.	**522180**	Savings Institutions and Other Depository Credit Intermediation
522190	Other Depository Credit Intermediation	pt.	**522180**	Savings Institutions and Other Depository Credit Intermediation
522293	International Trade Financing	pt.	**522299**	International, Secondary Market, and All Other Nondepository Credit Intermediation
522294	Secondary Market Financing	pt.	**522299**	International, Secondary Market, and All Other Nondepository Credit Intermediation
522298	All Other Nondepository Credit Intermediation	pt.	**522299**	International, Secondary Market, and All Other Nondepository Credit Intermediation
523110	Investment Banking and Securities Dealing	pt.	**523150**	Investment Banking and Securities Intermediation
523120	Securities Brokerage	pt.	**523150**	Investment Banking and Securities Intermediation
523130	Commodity Contracts Dealing	pt.	**523160**	Commodity Contracts Intermediation
523140	Commodity Contracts Brokerage	pt.	**523160**	Commodity Contracts Intermediation
523920	Portfolio Management	pt.	**523940**	Portfolio Management and Investment Advice
523930	Investment Advice	pt.	**523940**	Portfolio Management and Investment Advice
524292	Third Party Administration of Insurance and Pension Funds	nt.	524292	Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds
541380	Testing Laboratories	nt.	541380	Testing Laboratories and Services
541850	Outdoor Advertising	nt.	541850	Indoor and Outdoor Display Advertising
561611	Investigation Services	nt.	561611	Investigation and Personal Background Check Services
624410	Child Day Care Services	nt.	624410	Child Care Services
811112	Automotive Exhaust System Repair	pt.	**811114**	Specialized Automotive Repair
811113	Automotive Transmission Repair	pt.	**811114**	Specialized Automotive Repair
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	pt.	**811114**	Specialized Automotive Repair
811211	Consumer Electronics Repair and Maintenance	pt.	**811210**	Electronic and Precision Equipment Repair and Maintenance
811212	Computer and Office Machine Repair and Maintenance	pt.	**811210**	Electronic and Precision Equipment Repair and Maintenance
811213	Communication Equipment Repair and Maintenance	pt.	**811210**	Electronic and Precision Equipment Repair and Maintenance
811219	Other Electronic and Precision Equipment Repair and Maintenance	pt.	**811210**	Electronic and Precision Equipment Repair and Maintenance

Note: NAICS 2022 codes in bold indicate pieces of the NAICS 2022 industry came from more than one NAICS 2017 industry; NAICS 2017 codes in italics indicate the NAICS 2017 industry split to two or more NAICS 2022 industries.

Key to abbreviations:

pt. = Part of NAICS 2022 United States industry (n = 217). If a NAICS 2017 industry is split into multiple NAICS 2022 industries, it is counted k times where k is the number of NAICS 2022 industries which includes part of that industry.
nc. = 6-digit NAICS codes changed without changing industries' titles (n = 11).
nt. = NAICS industry titles amended without changing the 6-digit codes (n = 15).
nct. = Either 6-digit codes, title, or content changed (n = 6).
n = Number of industries.

Size Standards for New Industries in NAICS 2022

On October 22, 1999, SBA proposed to replace SIC with NAICS 1997 as the basis of industry definitions for its table of small business size standards (64 FR 57188). The proposed rule included a set of guidelines or rules that SBA applied to convert the size standards for industries under SIC to industries under NAICS. The guidelines primarily aimed to minimize the impact of applying a new industry classification system on SBA's size standards and on small businesses that qualified as small under the SIC-based size standards. SBA received no negative comments against the proposed guidelines. Thus, SBA published its final rule on May 15, 2000 (65 FR 30386), corrected on September 5, 2000 (65 FR 53533), adopting the resulting table of size standards based on NAICS 1997 structure, as proposed. To be consistent, SBA generally applied the same guidelines when it updated its table of size standards to adopt NAICS 2002, NAICS 2007, NAICS 2012, and NAICS 2017 revisions. In those updates as well, SBA received no adverse comments against using those guidelines, or against the resulting changes to the size standards. These guidelines to adopt NAICS revisions for size standards were also included in the SBA's ''Size Standards Methodology'' white paper and SBA received no adverse comments when the revised methodology was open for public comments. Accordingly, for the July 5, 2022, proposed rule to adopt NAICS 2022 structure for its size standards table as well, SBA generally followed the same guidelines, as shown below in Table 5, ''General Guidelines to Establish Size Standards for New Industries under NAICS 2022.''

Table 5

General Guidelines to Establish Size Standards for New Industries under NAICS 2022

	If the NAICS 2022 industry is composed of:	The size standard for the NAICS 2022 industry code will be:
1	A single NAICS 2012 industry or part of a single NAICS 2012 industry	The same size standard as for the NAICS 2012 industry or part.
2	Two or more NAICS 2017 industries; two or more parts of an NAICS 2017 industry; parts of two or more NAICS 2017 industries; or one or more NAICS 2017 industries and part(s) of one or more NAICS 2017 industries, and	
	2a. they all have the same size standard	The same size standard as for the NAICS 2017 industries or parts.
	2b. they all have the same size measure (*e.g.*, receipts, employees, etc.) but do not all have the same size standard	The same size standard as for the NAICS 2017 industry or part that most closely matches the economic activity described by the NAICS 2022 industry, or The highest size standard among the NAICS 2017 industries and part(s) that comprise the NAICS 2022 industry, provided that the highest size standard does not include dominant or potentially dominant firms.
	2c. they have different size measures (i.e., for example, some are based on receipts and others on employees) and hence do not all have the same size standard	The same size standard as for the NAICS 2017 industry or part that most closely matches the economic activity described by the NAICS 2022 industry, or The highest size standard among the NAICS 2017 industries and part(s) that comprise the NAICS 2022 industry, provided that the highest size standard does not include dominant or potentially dominant firms. To apply this rule, SBA converts all size standards to a single measure (e.g., receipts, employees, etc.) using the size measure for the NAICS 2017 industry or part(s) that most closely match the economic activity described by the NAICS 2022 industry or using the size measure that applies to most of the NAICS industries or parts comprising the NAICS 2022 industry.

SBA generally applied the guidelines in Table 5 to convert the size standards from NAICS 2017 industries to NAICS 2022 industries. In addition to following the above general guidelines in Table 5, in cases where a new industry is formed by merging multiple industries or parts of multiple industries with substantially different levels or measures of size

standards, as detailed in the July 5, 2022, proposed rule, SBA also examined the relevant latest industry and Federal procurement data to determine an appropriate size standard for the new industry. Developed based on the above guidelines and analyses of the relevant data, where necessary, SBA's size standards for the new industries under NAICS 2022 are shown in Table 6, Size Standards for New Industries in NAICS 2022.'' Also shown in Table 6 are the current size standards for the affected NAICS 2017 industries and their parts.

Following the publication of the July 5, 2022, proposed rule to incorporate NAICS 2022 into the SBA's table of size standards, as part of the second five-year review of size standards under the Small Business Jobs Act of 2010 (Jobs Act) (Pub. L. 111–240 (September 27, 2010)), SBA adopted revisions to size standards for industries under NAICS Sectors 42 (Wholesale Trade) and 44–45 (Retail Trade), effective July 14, 2014 (87 FR 35869 (June 14, 2022)). Accordingly, in this final rule, SBA is adjusting proposed size standards for the new industries under NAICS 2022 to reflect new size standards for Sectors 42 and 44–45 the Agency adopted in the June 14, 2022, final rule. Table 6 shows the adjusted size standards.

Table 6
Size Standards for New Industries in NAICS 2017

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
212111	Bituminous Coal and Lignite Surface Mining		1,250		1,250	**212114**	Surface Coal Mining	N
212113	Anthracite Mining - *anthracite surface mining*		250					
212112	Bituminous Coal Underground Mining		1,500		1,500	**212115**	Underground Coal Mining	N
212113	Anthracite Mining - *anthracite underground mining*		250					
212221	Gold Ore Mining		1,500		1,500	**212220**	Gold Ore and Silver Ore Mining	N
212222	Silver Ore Mining		250					
212291	Uranium-Radium-Vanadium Ore Mining		250		750	**212290**	Other Metal Ore Mining	N
212299	All Other Metal Ore Mining		750					
212324	Kaolin and Ball Clay Mining		750		500	**212323**	Kaolin, Clay, and Ceramic and Refractory Minerals Mining	N
212325	Clay and Ceramic and Refractory Minerals Mining		500					
212391	Potash, Soda, and Borate Mineral Mining		750		500	**212390**	Other Nonmetallic Mineral Mining and Quarrying	N
212392	Phosphate Rock Mining		1,000					
212393	Other Chemical and Fertilizer Mineral Mining		500					
212399	All Other Nonmetallic Mineral Mining		500					
311221	Wet Corn Milling		1,250		1,250	311221	Wet Corn Milling and Starch Manufacturing	nt.
315110	Hosiery and Sock Mills		750		750	**315120**	Apparel Knitting Mills	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
315190	Other Apparel Knitting Mills		750					
315220	Men's and Boys' Cut and Sew Apparel Manufacturing		750		750	**315250**	Cut and Sew Apparel Manufacturing (except Contractors)	N
315240	Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing		750					
315280	Other Cut and Sew Apparel Manufacturing		750					
316992	Women's Handbag and Purse Manufacturing		750		500	**316990**	Other Leather and Allied Product Manufacturing	N
316998	All Other Leather Good and Allied Product Manufacturing		500					
321213	Engineered Wood Member (except Truss) Manufacturing		750		500	**321215**	Engineered Wood Member Manufacturing	N
321214	Truss Manufacturing		500					
322121	Paper (except Newsprint) Mills		1,250		1,250	**322120**	Paper Mills	N
322122	Newsprint Mills		750					
325314	Fertilizer (Mixing Only) Manufacturing - *except compost manufacturing*		500		500	325314	Fertilizer (Mixing Only) Manufacturing	nct.
325314	Fertilizer (Mixing Only) Manufacturing - *compost manufacturing*		500		500	325315	Compost Manufacturing	nct.
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing		1,500		1,500	325992	Photographic Film, Paper, Plate, Chemical, and Copy Toner Manufacturing	nt.
333244	Printing Machinery and Equipment Manufacturing		750		750	**333248**	All Other Industrial Machinery Manufacturing	N
333249	Other Industrial Machinery Manufacturing		500					

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
333314	Optical Instrument and Lens Manufacturing		500		1,000	**333310**	Commercial and Service Industry Machinery Manufacturing	N
333316	Photographic and Photocopying Equipment Manufacturing		1,000					
333318	Other Commercial and Service Industry Machinery Manufacturing		1,000					
333997	Scale and Balance Manufacturing		500		500	**333998**	All Other Miscellaneous General Purpose Machinery Manufacturing	N
333999	All Other Miscellaneous General Purpose Machinery Manufacturing		500					
334613	Blank Magnetic and Optical Recording Media Manufacturing		1,000		1,250	**334610**	Manufacturing and Reproducing Magnetic and Optical Media	N
334614	Software and Other Prerecorded Compact Disc, Tape, and Record Reproducing		1,250					
335121	Residential Electric Lighting Fixture Manufacturing		750		750	335131	Residential Electric Lighting Fixture Manufacturing	nc.
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing		500		500	335132	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	nc.
335110	Electric Lamp Bulb and Part Manufacturing		1,250		1,250	**335139**	Electric Lamp Bulb and Other Lighting Equipment Manufacturing	N
335129	Other Lighting Equipment Manufacturing		500					
335911	Storage Battery Manufacturing		1,250		1,250	**335910**	Battery Manufacturing	N
335912	Primary Battery Manufacturing		1,000					
336111	Automobile Manufacturing		1,500		1,500	**336110**	Automobile and Light Duty Motor Vehicle Manufacturing	N
336112	Light Truck and Utility Vehicle Manufacturing		1,500					
337124	Metal Household Furniture Manufacturing		750		750	**337126**	Household Furniture (except Wood and Upholstered) Manufacturing	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
337125	Household Furniture (except Wood and Metal) Manufacturing		750					
424320	Men's and Boys' Clothing and Furnishings Merchant Wholesalers		150		150	**424350**	Clothing and Clothing Accessories Merchant Wholesalers	N
424330	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers		100					
424940	Tobacco and Tobacco Product Merchant Wholesalers		250		250	424940	Tobacco Product and Electronic Cigarette Merchant Wholesalers	nt.
425110	Business to Business Electronic Markets		125		125	**425120**	Wholesale Trade Agents and Brokers	N
425120	Wholesale Trade Agents and Brokers		125					
441228	Motorcycle, ATV, and All Other Motor Vehicle Dealers	$35.0		$35.0		**441227**	Motorcycle, ATV, and All Other Motor Vehicle Dealers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
441310	Automotive Parts and Accessories Stores	$25.0		$25.0		**441330**	Automotive Parts and Accessories Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
441320	Tire Dealers	$22.5		$22.5		**441340**	Tire Dealers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
444120	Paint and Wallpaper Stores	$30.0		$30.0		444120	Paint and Wallpaper Retailers	nt.
444130	Hardware Stores	$14.5		$14.5		**444140**	Hardware Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454390	Other Direct Selling Establishments	$13.0						
444190	Other Building Material Dealers	$22.0		$22.0		**444180**	Other Building Material Dealers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
444210	Outdoor Power Equipment Stores	$8.5		$8.5		**444230**	Outdoor Power Equipment Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
444220	Nursery, Garden Center, and Farm Supply Stores	$19.0		$19.0		**444240**	Nursery, Garden Center, and Farm Supply Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
445110	Supermarkets and Other Grocery (except Convenience) Stores	$35.0		$35.0		445110	Supermarkets and Other Grocery Retailers (except Convenience) Retailers	nt.
445120	Convenience Stores	$32.0		$32.0		**445131**	Convenience Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
454210	Vending Machine Operators	$18.5		$18.5		445132	Vending Machine Operators	nc.
445230	Fruit and Vegetable Markets	$8.0		$8.0		445230	Fruit and Vegetable Retailers	nt.
445210	Meat Markets	$8.0		$8.0		**445240**	Meat Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
445220	Fish and Seafood Markets	$8.0		$8.0		**445250**	Fish and Seafood Retailers	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
445291	Baked Goods Stores	$14.0		$14.0		445291	Baked Goods Retailers	nt.
445292	Confectionery and Nut Stores	$17.0		$17.0		445292	Confectionery and Nut Retailers	nt.
445299	All Other Specialty Food Stores	$9.0		$9.0		**445298**	All Other Specialty Food Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
445310	Beer, Wine, and Liquor Stores	$9.0		$9.0		**445320**	Beer, Wine, and Liquor Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
442110	Furniture Stores	$22.0		$22.0		**449110**	Furniture Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
442210	Floor Covering Stores	$8.0		$8.0		**449121**	Floor Covering Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0.0						
442291	Window Treatment Stores	$10.0		$10.0		**449122**	Window Treatment Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
442299	All Other Home Furnishings Stores	$29.5		$29.5		**449129**	All Other Home Furnishings Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
443141	Household Appliance Stores	$19.5		$35.0		**449210**	Electronics and Appliance Retailers	N
443142	Electronics Stores	$35.0						

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
452210	Department Stores	$35.0		$35.0		**455110**	Department Stores	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
452311	Warehouse Clubs and Supercenters	$41.5		$41.5		**455211**	Warehouse Clubs and Supercenters	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
452319	All Other General Merchandise Stores	$35.0		$35.0		**455219**	All Other General Merchandise Retailers	N
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *general merchandise auction houses*	$10.0						
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
446110	Pharmacies and Drug Stores	$33.0		$33.0		**456110**	Pharmacies and Drug Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
446120	Cosmetics, Beauty Supplies, and Perfume Stores	$30.0		$30.0		**456120**	Cosmetics, Beauty Supplies, and Perfume Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
446130	Optical Goods Stores	$26.0		$26.0		**456130**	Optical Goods Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
446191	Food (Health) Supplement Stores	$20.0		$20.0		**456191**	Food (Health) Supplement Retailers	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
446199	All Other Health and Personal Care Stores	$8.5		$8.5		**456199**	All Other Health and Personal Care Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
447110	Gasoline Stations with Convenience Stores	$32.0		$32.0		457110	Gasoline Stations with Convenience Stores	nc.
447190	Other Gasoline Stations	$29.5		$29.5		457120	Other Gasoline Stations	nc.
454310	Fuel Dealers		100		100	457210	Fuel Dealers	nc.
448110	Men's Clothing Stores	$22.5		$41.5		**458110**	Clothing and Clothing Accessories Retailers	N
448120	Women's Clothing Stores	$30.0						
448130	Children's and Infants' Clothing Stores	$35.0						
448140	Family Clothing Stores	$41.5						
448150	Clothing Accessories Stores	$29.5						
448190	Other Clothing Stores	$27.5						
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
448210	Shoe Stores	$30.0		$30.0		**458210**	Shoe Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
448310	Jewelry Stores	$18.0		$18.0		**458310**	Jewelry Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
448320	Luggage and Leather Goods Stores	$33.5		$33.5		**458320**	Luggage and Leather Goods Retailers	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
451110	Sporting Goods Stores	$23.5		$23.5		**459110**	Sporting Goods Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
451120	Hobby, Toy, and Game Stores	$31.0		$31.0		**459120**	Hobby, Toy, and Game Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
451130	Sewing, Needlework, and Piece Goods Stores	$30.0		$30.0		**459130**	Sewing, Needlework, and Piece Goods Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
451140	Musical Instrument and Supplies Stores	$20.0		$20.0		**459140**	Musical Instrument and Supplies Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
451211	Book Stores	$31.5		$31.5		**459210**	Book Retailers and News Dealers	N
451212	News Dealers and Newsstands	$20.0						
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453110	Florists	$8.0		$8.0		**459310**	Florists	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453210	Office Supplies and Stationery Stores	$35.0		$35.0		**459410**	Office Supplies and Stationery Retailers	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453220	Gift, Novelty, and Souvenir Stores	$12.0		$12.0		**459420**	Gift, Novelty, and Souvenir Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453310	Used Merchandise Stores	$12.5		$12.5		**459510**	Used Merchandise Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453910	Pet and Pet Supplies Stores	$28.0		$28.0		**459910**	Pet and Pet Supplies Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453920	Art Dealers	$14.5		$14.5		**459920**	Art Dealers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
453930	Manufactured (Mobile) Home Dealers	$16.5		$16.5		459930	Manufactured (Mobile) Home Dealers	nc.
453991	Tobacco Stores	$8.0		$10.0		**459991**	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers	N
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *electronic cigarette stores and marijuana stores, medical or recreational*	$10.0						
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores) - *except general merchandise auction houses, electronic cigarette stores, and marijuana stores, medical or recreational*	$10.0		$10.0		**459999**	All Other Miscellaneous Retailers	N
454110	Electronic Shopping and Mail-Order Houses	$41.5						
454390	Other Direct Selling Establishments	$13.0						
485310	Taxi Service	$16.5		$16.5		485310	Taxi and Ridesharing Services	nt.
511110	Newspaper Publishers		1,000		1,000	**513110**	Newspaper Publishers	N
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet newspaper publishers*		1,000					
511120	Periodical Publishers		1,000		1,000	**513120**	Periodical Publishers	N
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet periodical publishers*		1,000					
511130	Book Publishers		1,000		1,000	**513130**	Book Publishers	N
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet book publishers*		1,000					
511140	Directory and Mailing List Publishers		1,250		1,000	**513140**	Directory and Mailing List Publishers	N
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet directory and mailing list publishers*		1,000					
511191	Greeting Card Publishers		1,500		1,000	**513191**	Greeting Card Publishers	N

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet greeting card publishers*		1,000					
511199	All Other Publishers		500		1,000	**513199**	All Other Publishers	N
519130	Internet Publishing and Broadcasting and Web Search Portals - *all other Internet publishers*		1,000					
511210	Software Publishers	$41.5		$41.5		513210	Software Publishers	nc.
515112	Radio Stations	$41.5		$41.5		516110	Radio Broadcasting Stations	nct.
515120	Television Broadcasting - *television broadcasting stations*	$41.5		$41.5		516120	Television Broadcasting Stations	nct.
515111	Radio Networks	$41.5		$41.5		**516210**	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers	N
515120	Television Broadcasting - *television networks*	$41.5						
515210	Cable and Other Subscription Programming	$41.5						
519110	News Syndicates	$32.0						
519130	Internet Publishing and Broadcasting and Web Search Portals - *Internet broadcasting*		1,000					
517311	Wired Telecommunications Carriers		1,500		1,500	517111	Wired Telecommunications Carriers	nc.
517312	Wireless Telecommunications Carriers (except Satellite) - *except agents for wireless telecommunications carriers*		1,500		1,500	517112	Wireless Telecommunications Carriers (except Satellite)	nct.
517911	Telecommunications Resellers - *except agents for wireless telecommunications resellers*		1,500		1,500	517121	Telecommunications Resellers	nct.

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
517312	Wireless Telecommunications Carriers (except Satellite) - *agents for wireless telecommunications carriers*		1,500		1,500	**517122**	Agents for Wireless Telecommunications Services	N
517911	Telecommunications Resellers - *agents for wireless telecommunications resellers*		1,500					
517919	All Other Telecommunications	$35.0		$35.0		517810	All Other Telecommunications	nc.
518210	Data Processing, Hosting, and Related Services	$35.0		$35.0		518210	Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services	nt.
519120	Libraries and Archives	$18.5		$18.5		519210	Libraries and Archives	nc.
519130	Internet Publishing and Broadcasting and Web Search Portals - *web search portals*		1,000		1,000	**519290**	Web Search Portals and All Other Information Services	N
519190	All Other Information Services	$30.0						
522120	Savings Institutions	$750.0 million in assets		$750.0 million in assets		**522180**	Savings Institutions and Other Depository Credit Intermediation	N
522190	Other Depository Credit Intermediation	$750.0 million in assets						
522293	International Trade Financing	$41.5		$41.5		**522299**	International, Secondary Market, and All Other Nondepository Credit Intermediation	N
522294	Secondary Market Financing	$41.5						
522298	All Other Nondepository Credit Intermediation	$41.5						
523110	Investment Banking and Securities Dealing	$41.5		$41.5		**523150**	Investment Banking and Securities Intermediation	N
523120	Securities Brokerage	$41.5						
523130	Commodity Contracts Dealing	$41.5		$41.5		**523160**	Commodity Contracts Intermediation	N
523140	Commodity Contracts Brokerage	$41.5						
523920	Portfolio Management	$41.5		$41.5		**523940**	Portfolio Management and Investment Advice	N
523930	Investment Advice	$41.5						

NAICS 2017 Code	NAICS 2017 U.S. Industry Title *(and specific piece of the NAICS 2017 industry that is contained in the NAICS 2022 industry)*	Current NAICS 2017 Standard ($million)	Current NAICS 2017 Standard (employees)	Adopted NAICS 2022 Standard ($million)	Adopted NAICS 2022 Standard (employees)	NAICS 2022 Code	NAICS 2022 U.S. Industry Title	Status code
524292	Third Party Administration of Insurance and Pension Funds	$40.0		$40.0		524292	Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds	nt.
541380	Testing Laboratories	$16.5		$16.5		541380	Testing Laboratories and Services	nt.
541850	Outdoor Advertising	$30.5		$30.5		541850	Indoor and Outdoor Display Advertising	nt.
561611	Investigation Services	$22.0		$22.0		561611	Investigation and Personal Background Check Services	nt.
624410	Child Day Care Services	$8.5		$8.5		624410	Child Care Services	nt.
811112	Automotive Exhaust System Repair	$8.0		$8.0		**811114**	Specialized Automotive Repair	N
811113	Automotive Transmission Repair	$8.0						
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$8.0						
811211	Consumer Electronics Repair and Maintenance	$22.5		$30.0		**811210**	Electronic and Precision Equipment Repair and Maintenance	N
811212	Computer and Office Machine Repair and Maintenance	$30.0						
811213	Communication Equipment Repair and Maintenance	$19.5						
811219	Other Electronic and Precision Equipment Repair and Maintenance	$22.0						

Note: NAICS 2022 codes in bold indicate pieces of the NAICS 2022 industry came from more than one NAICS 2017 industry; NAICS 2017 codes in italics indicate the NAICS 2017 industry split to two or more NAICS 2022 industries.

Key to abbreviations:

N = New industry (in **bold**) formed by combining two or more of NAICS 2017 industries or their parts.
nc. = 6-digit NAICS codes changed without changing industries' titles.
nt. = NAICS industry titles amended without changing the 6-digit codes.
nct. = Either 6-digit codes, titles, or contents changed.

Summary of Size Standards for NAICS 2022 Industries

The NAICS 2022 revision created 111 new industries by reclassifying, combining, or splitting 156 NAICS 2017 industries or their parts. SBA's size standards for these 111 new industries under NAICS 2022, as shown in Table 3 (above) have resulted in an increase to the size standards for 22 industries and 29 parts of two industries under NAICS 2017, a decrease to size standards for seven industries and 53 parts of two industries, a change in the size standard measure from average annual receipts to number of employees for one industry, a change in the size standard measure from number of employees to average annual receipts for part of one industry, and no change in size standards for 117 industries and 19 parts of seven industries. These figures are slightly different from those published in the proposed rule because of the adoption of the latest size standards for industries in Sectors 42 and 44–45 that became effective on July 14, 2022 (87 FR 35869).[2]

In accordance with 13 CFR 121.102(e), SBA advises eligible parties of the option to file a petition for reconsideration of a revised, modified, or established size standard at SBA's Office of Hearings and Appeals (OHA) within 30 calendar days after publication of this final rule in accordance with 15 U.S.C. 632(a)(9) and 13 CFR 134 Subpart I. OHA can be reached using the following contact information: by mail at U.S. Small Business Administration, Office of Hearings and Appeals, 409 Third St. SW, Eighth Floor, Washington, DC 20416, by email at *ohafilings@sba.gov* by phone: 202–401–8200 TTY/TRS: 711, *or by* fax at (202) 205–7059.

Discussion of Comments

For the July 5, 2022, proposed rule, SBA provided a 30-day comment period for the public to comment on proposed changes to size standards from the adoption of the NAICS 2022, which ended on August 4, 2022. SBA sought comment on whether its proposed size standards for new industries under NAICS 2022 were appropriate and suggestions on alternative size standards, along with supporting data and analysis, if proposed size standards were not appropriate. SBA also sought comments on its methodology for converting size standards from NAICS 2017 to NAICS 2022 and data sources and analyses it used in developing proposed size standards for new industries. SBA received three comments, which are summarized and discussed below.

Comments on Correct Size Standards

SBA received one comment contending that the Agency did not propose the latest size standards it updated on July 14, 2022 for three NAICS codes, namely NAICS 425120 (Wholesale Trade Agents and Brokers), NAICS 445291 (Baked Goods Stores), and NAICS 445292 (Confectionery and Nut Stores). The commenter urged the SBA to use the most recent size standards for these NAICS codes.

SBA Response

Following the publication of the July 5, 2022, proposed rule to adopt NAICS 2022 for size standards, as part of the second five-year review of size standards under the Jobs Act, SBA adopted size standards revisions for industries under NAICS Sectors 42 and 44–45, effective July 14, 2022. At the time when SBA published the NAICS 2022 proposed rule, the old size standards were in effect. Thus, SBA applied the old size standards in the proposed rule. In this final rule, however, SBA is adopting the July 14, 2022, version of the size standards as shown in Table 6 (above) and Table 7, Adopted Size Standards for NAICS 425120, 445291 and 445292, below, which are the latest size standards in effect.

Table 7
Adopted Size Standards for NAICS 425120, 445291 and 445292

NAICS 2017 code	NAICS 2017 Industry Title	Proposed (Old) Size Standard	NAICS 2022 Code	NAICS 2022 Industry Title	Adopted (New) Size Standard
4215110	Business to Business Electronic Markets	100 employees	425120	Wholesale Trade Agents and Brokers	125 employees
425120	Wholesale Trade Agents and Brokers	100 employees			
445291	Baked Goods Stores	$8 million	445291	Baked Goods Retailers	$14 million
445292	Confectionary and Nuts Stores	$8 million	445292	Confectionary and Nuts Retailers	$17 million

[2] In the proposed rule, SBA's proposed size standards for the 111 new industries under NAICS 2022 resulted in an increase to the size standards for 21 industries and 27 parts of three industries under NAICS 2017, a decrease to size standards for seven industries and 41 parts of one industry, a change in the size standard measure from average annual receipts to number of employees for one industry, a change in the size standard measure from number of employees to average annual receipts for a part of one industry, and no change in size standards for 118 industries and 33 parts of eight industries.

Comments on Missing NAICS Codes

SBA received a comment stating that the proposed rule did not mention three NAICS codes added for the 2022 NAICS revision, namely NAICS 521110 (Monetary Authorities-Central Bank), NAICS 541120 (Offices of Notaries), and NAICS, 551114 (Corporate, Subsidiary, and Regional Managing Offices). These are found on the Economic Census NAICS website (*https://www.census.gov/naics*), the commenter added.

SBA Response

SBA disagrees with the commenter that NAICS codes 521110, 541120, and 551114 were newly added to NAICS 2022. These NAICS codes existed since the initial, 1997 edition of NAICS, which replaced the Standard Industry Classification (SIC) system as the basis of industry definitions for size standards. Table 8, NAICS–SIC Concordance for NAICS 521110, 541120, and 551114, shows the relationship between NAICS and SIC with respect to these three NAICS codes. When SBA first switched from SIC to NAICS as the basis of industry definitions for size standards, it did not establish small business size standards for these NAICS codes for the following reasons.

Table 8

NAICS-SIC Concordance for NAICS 521110, 541120, and 551114

1997 NAICS	1997 NAICS Title	SIC	SIC Title and Part Description
521110	Monetary Authorities - Central Bank	6011	Federal Reserve Banks
541120	Offices of Notaries		Null Set for U.S.
551114	Corporate, Subsidiary, and Regional Managing Offices	Aux	These establishments were included as auxiliaries in the 1987 Standard Industrial Classification

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NAICS 521110—Monetary Authorities-Central Bank

In the United States, the functions of the Monetary Authorities-Central Bank are performed by the Federal Reserve System. According to the NAICS manual, found at *www.census.gov/naics,* establishments of the Board of Governors of the Federal Reserve System are classified in NAICS Industry 921130, Public Finance Activities. As stated in Footnote 17 to the SBA's table of size standards, small business size standards are not established for industries within NAICS Sector 92, Public Administration.

NAICS 541120—Offices of Notaries

As shown in Table 8 (above), NAICS Industry 541120 (Offices of Notaries) is not a valid industry in the United States and accordingly SBA does not establish the small business size standard for that NAICS code. According to the NAICS manual, available at *www.census.gov/naics,* establishments of notaries public engaged in activities, such as administering oaths and taking affidavits and depositions, witnessing and certifying signatures on documents, but not empowered to draw and approve legal documents and contracts, are classified in U.S. NAICS Industry 541199, All Other Legal Services. Moreover, NAICS 541120 is not covered by both the Economic Census and County Business Patterns Reports.

NAICS 551114—Corporate, Subsidiary, and Regional Managing Offices

As shown in Table 8 (above), NAICS Industry 551114 did not correspond to any specific industry under SIC. As a result, when SBA first established size standards for NAICS industries, the Agency did not establish a small business size standard for NAICS 551114. The adoptions of the subsequent NAICS revisions also did not assign the size standard for NAICS 551114. Like NAICS 541120, NAICS 55114 is also not covered by both the Economic Census and County Business Patterns Reports.

Comments on Inflation Adjustment of Revenue-Based Size Standards

SBA received a comment urging SBA to adjust all revenue-based size standards for inflation. The commenter maintained that current inflation is running at 9.1% and that inflation adjustment of size standards by that amount is appropriate in the current economic environment.

SBA Response

SBA is required to assess the impact of inflation on its monetary-based size standards *at least* once every five years (67 FR 3041 (January 23, 2002)) and 13 CFR 121.102(c)) and make necessary adjustments to restore their values in real terms. As stated in the SBA's Semiannual Regulatory Agenda for Spring 2022, SBA is currently pursuing a separate rulemaking (RIN 3245–AH93) to assess the impact of the current general price increases on size standards. SBA agrees with the comment that current inflation trends warrant adjustment of monetary-based size standards for inflation. SBA expects to issue that rulemaking in the near future.

Conclusion

In absence of adverse comments against the proposed size standards for the new industries under NAICS 2022, SBA is adopting the size standards for the new industries, as proposed.

Evaluation of Dominance in Field of Operation

Section 3(a) of the Small Business Act (15 U.S.C. 632(a)) defines a small business concern as one that: (1) Is independently owned and operated; (2) Is not dominant in its field of operation; and (3) Meets a specific small business definition or size standard established by SBA's Administrator. SBA considers, as part of its evaluation, whether a business concern at a proposed or revised size standard would be dominant in its field of operation. For this, SBA generally examines the industry's market share of firms at the proposed or revised standard. SBA also examines distribution of firms by size to

ensure that a contemplated size standard excludes the largest and potentially dominant firms within an industry. The results of the market share analysis and size distribution of firms may indicate whether a firm, at the proposed or revised size standard, can exercise a control on a national basis. SBA has determined that for the industries for which size standards have been changed in this proposed rule, no individual firm at or below the proposed size standard will be large enough to dominate its field of operation. The share of a firm in total industry receipts at the proposed size standard, among those industries for which size standards have been changed is, on average, 1.8%, ranging from 0.005% to 31.2%. SBA determines that these levels of market shares effectively preclude a firm at or below the proposed size standards from exerting control on any of the industries.

Alternatives To Adopting NAICS 2022 for Size Standards

As an alternative to adopting new size standards for NAICS 2022 industries, in this final rule, SBA considered retaining NAICS 2017 as the basis of industry definitions for its small business size standards. That would, however, lead to inconsistency between SBA's size standards and establishment data published by Federal agencies that will adopt NAICS 2022 for their statistical and other data collection programs. OMB stated in its December 21, 2021, notice that ''Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using the 2022 NAICS United States codes.'' SBA is not a statistical agency, but the Agency uses for its size standards analyses establishment data collected by other Federal agencies, such as the Economic Census data and County Business Patterns from the U.S. Census Bureau. If SBA continues using NAICS 2017 for its size standards, it will not be able to analyze and evaluate industry structure adequately and accurately and adjust small business size standards appropriately because the forthcoming Economic Census and County Business Patterns data based on NAICS 2022 will not be compatible with NAICS 2017. That would run counter to the mandate of the Jobs Act, which requires SBA to review all size standards and adjust them appropriately to reflect the current industry and market data every five years.

To establish, review, or revise, where necessary, small business size standards, SBA uses special tabulations of industry data that it obtains from the U.S. Census Bureau based on its Economic Census of U.S. industries and businesses, and establishment data from its County Business Patterns. Because the 2022 Economic Census will be based on NAICS 2022 industry definitions, it is imperative that SBA use NAICS 2022 as the basis of industry definitions for its table of small business size standards.

Justification for the October 1, 2022, Effective Date

The Administrative Procedure Act (APA) requires that ''publication or service of a substantive rule shall be made not less than 30 days before its effective date, except * * * as otherwise provided by the agency for good cause found and published with the rule.'' 5 U.S.C. 553(d)(3). The purpose of the APA provision delaying the effective date of a rule for 30 days after publication is to provide interested and affected members of the public sufficient time to adjust their behavior before the rule takes effect. For the reasons set forth below, SBA finds that good cause exists to make this final rule become effective on October 1, 2022, less than 30 days after it is published in the **Federal Register**.

SBA's small business size standards, matched to NAICS 2022, to be adopted in a forthcoming final rule, will be effective on October 1, 2022, for the following reasons:

1. OMB stated in its December 21, 2021, notice that Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using NAICS 2022. SBA is not a statistical agency, but it uses the establishment data collected from other Federal agencies, such as the Economic Census and County Business Patterns data from the Census Bureau for its size standards analysis. Similarly, Federal procurement databases and systems, such as FPDS–NG and the System for Award Management (SAM), use NAICS codes from SBA's table of size standards. If SBA does not adopt NAICS 2022 for its table of size standards in a timely manner, it will result in inconsistency between SBA's size standards and other Federal procurement databases.

Small business size standards apply to most Federal agencies and their programs involving small businesses; the time lag between the OMB's effective date and SBA's update to its size standards has already given them time to implement the changes and develop training tools, if necessary; so further additional time to prepare to comply is unnecessary.

2. October 1, 2022, is the start of the new Federal Government fiscal year following OMB's adoption of NAICS 2022 effective January 1, 2022, and is consistent with SBA's adoption of previous NAICS revisions for its size standards effective at the beginning of the new fiscal year after the OMB's effective date. Like the adoption of the previous NAICS revisions, the adoption of NAICS 2022 is ''not significant'' and noncontroversial, as SBA is merely implementing the revised NAICS codes promulgated by OMB through a comment and notice process.

3. With the adoption of the updated size standards at the start of the new fiscal year (October 1, 2022), instead of the OMB January 1, 2022, effective date, Federal agencies that use NAICS industry definitions and SBA's size standards can collect comparable and consistent data on Federal statistics for program and industry analyses.

4. With the October 1, 2022, effective date, Federal agencies that use SBA's small business size standards for their programs will have sufficient time to plan and implement the updated size standards and assess the impact of size standards changes on their programs.

Compliance With Executive Orders 12866, the Congressional Review Act (5 U.S.C. 801–808), the Regulatory Flexibility Act (5 U.S.C. 601–612), Executive Orders 13563, 12988, and 13132, and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

Executive Order 12866

OMB has determined that this final rule is not a ''significant regulatory action'' for purposes of Executive Order 12866. This rule incorporates the OMB's 2022 revisions of NAICS, which SBA uses as a basis of industry definitions for purposes of establishing small business size standards. As discussed above in the Supplementary Information section, the size standards of some industries or their parts would change because of the adoption of the NAICS 2022 revisions for SBA's Table of Size Standards. However, SBA has determined that a vast majority of businesses defined as small under the current NAICS 2017 based size standards will continue to remain small under the NAICS 2022 based size standards. The final rule will also affect other Federal Government programs that use SBA's size standards and provide various benefits for small businesses. In order to help explain the need and objective of this proposed rule and its potential benefits and costs, SBA is providing, below, a Cost Benefit Analysis of this final rule, including (1)

A statement of the need for the regulatory action, (2) An examination of alternative approaches, and (3) An evaluation of the benefits and costs—both quantitative and qualitative—of the regulatory action and the alternatives considered.

Cost Benefit Analysis

1. *What is the need for the regulatory action?*

SBA believes that revising its small business size standards based on NAICS 2022 is in the best interests of small businesses. SBA's mission is to aid and assist small businesses through a variety of financial, procurement, business development and counselling, and advocacy programs. To ensure that these programs are best directed to their intended beneficiaries, SBA establishes numerical small business definitions (usually referred to as ''size standards'') to determine which businesses are deemed eligible for Federal small business assistance. NAICS 2022 provides the latest industry definitions reflecting the latest changes in industry structure in the United States.

Under the Small Business Act (Act) (15 U.S.C. 632(a)), the SBA Administrator is responsible for establishing small business size definitions and for ensuring that such definitions vary from industry to industry to reflect differences among various industries. By analyzing and reviewing size standards based on the NAICS 2022 industry definitions, SBA can more accurately and appropriately fulfill its mandate. If SBA does not use the latest industry definitions under NAICS 2022, size standards would not accurately reflect differences among industries. In addition, the Jobs Act requires SBA to review, at least every five years, all size standards and make necessary adjustments to reflect current industry and market conditions. To better serve this mandate, SBA needs to evaluate the industry data based on the latest NAICS industry definitions available.

In this final rule, SBA is generally following the same guidelines that it followed for adopting prior NAICS revisions for size standards, as spelled out under the Supplemental Information section. SBA also analyzed the relevant industry and program data to determine the size standards for certain NAICS 2022 industries involving NAICS 2017 industries or their parts with substantially different size standards. Size standards based on NAICS 2022 industry definitions and corresponding data will serve SBA's mission more effectively.

2. What are the potential benefits and costs of this regulatory action?

As stated previously, the NAICS 2022 revision created 111 new industries by reclassifying, combining, or splitting 156 NAICS 2017 industries or their parts. Changes from NAICS 2017 to NAICS 2022 consist of mergers of 125 NAICS 2017 industries or their parts to form the 79 new industries in NAICS 2022 with impacts on size standards on a number of NAICS 2017 industries. The NAICS 2022 revision also includes 32 changes in 6-digit codes, industry titles, or descriptions without changing the size standards. SBA's size standards for these 111 new industries under NAICS 2022 have resulted in an increase to the size standards for 22 industries and 29 parts of two industries, a decrease to size standards for seven industries and 53 parts of two industries, a change in the size standard measure from average annual receipts to number of employees for one industry, a change in the size standard measure from number of employees to average annual receipts for part of one industry, and no change in size standards for 117 industries and 19 parts of seven industries. The benefits, costs, and transfer impacts of these changes are discussed below.

OMB directs agencies to establish an appropriate baseline to evaluate any benefits, costs, or transfer impacts of new regulatory actions and alternative approaches considered. The baseline should represent the agency's best assessment of what the world would look like absent the regulatory action. For a regulatory action promulgating modifications to an existing regulation (such as modifying the existing size standards), a baseline assuming no change to the regulation (*i.e.,* making no changes to current size standards) would generally provide an appropriate benchmark for evaluating benefits, costs, or transfer impacts of proposed or final regulatory changes and their alternatives.

The Baseline

For purposes of this regulatory action, the baseline represents maintaining the ''status quo,'' *i.e.,* making no changes to the current size standards. Using the number of small businesses and levels of small business benefits (such as set-aside contracts, SBA's loans, disaster assistance, etc.) they receive under the current size standards as a baseline, one can examine the potential benefits, costs, and transfer impacts of changes to size standards on small businesses and on the overall economy.

Based on the 2017 Economic Census data, of a total of about 880,245 firms in the 156 impacted industries under NAICS 2017, 97.9% are considered small under the current size standards under NAICS 2017.

Similarly, based on the data from FPDS–NG for fiscal years 2018–2020, about 15,400 unique firms in those 156 NAICS 2017 industries received at least one Federal contract during that period, of which 76.2% were found to be small under the current size standards.[3] Of about $18.6 billion in total average annual contract dollars awarded to businesses in the impacted industries during that period, 25.6% went to small businesses. Of about $4.8 billion in total small business contract dollars awarded in those industries during that period, 87.1% were awarded through various set-aside programs and 12.9% were awarded through non-set aside contracts. Table 9, Baseline of Impacted Industries Under NAICS 2017, provides these baseline results.

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[3] Of the 156 NAICS 2017 industries impacted in the NAICS 2022 revision, 66 industries were part of Sector 42 (Wholesale Trade) or Sector 44–45 (Retail Trade) that does not apply for Federal contracting. In the remaining 90 industries that belong to other sectors, about 15,400 unique firms got at least one Federal contract during fiscal years 2018–2020.

Table 9
Baseline of Impacted Industries Under NAICS 2017

Impact variable	Value
Number of industries impacted	156
Total firms in impacted industries (2017 Economic Census)	880,245
Total small firms in impacted industries under current size standards (2017 Economic Census)	861,503
Small firms as % of total firms (2017 Economic Census)	97.9%
Total contract dollars ($ million) (FPDS-NG - fiscal years 2018-2020)	$18,644
Total small business contract dollars under current standards ($ million) (FPDS-NG - fiscal years 2018-2020)	$4,776
Small business dollars as % of total dollars (FPDS-NG fiscal years 2018-2020)	25.6%
Total number of unique firms getting contracts (FPDS-NG fiscal years 2018-2020)	15,391
Total number of unique small firms getting small business contracts (FPDS-NG fiscal years 2018-2020)	11,727
Small business firms as % of total firms (FPDS-NG fiscal years 2018-2020)	76.2%
Number of 7(a) and Certified Development Company (CDC)/504 loans (fiscal years 2018-2020)	8,316
Amount of 7(a) and CDC/504 loans ($ million) (fiscal years 2018-2020)	$4,789
Number of Economic Injury Disaster Loan (EIDL) program loans (fiscal years 2018-2020)[1]	589
Amount of EIDL loans ($ million) (fiscal years 2018-2020)[1]	$52.6

[1]Excludes COVID-19 related EIDL loans due to their temporary nature. Effective January 1, 2022, SBA stopped accepting applications for new COVID EIDL loans or advances.

Based on the SBA's internal data on its loan programs for fiscal years 2018–2020, small businesses in those 156 industries received, on an average annual basis, a total of 8,316 7(a) loans and CDC/504 loans in that period. That corresponded to about $4.8 billion in total loan amount, of which 85.8% was issued through the 7(a) loan guarantee program and 14.2% was issued through the CDC/504 program. During fiscal years 2018–2020, small businesses in those industries also received 589 loans through the SBA's EIDL program, totaling about $52.6 million on an annual basis.[4]

Increases to Size Standards

As stated above, SBA's size standards for the 111 new industries under NAICS 2022 have resulted in an increase to the size standards for 22 industries and 29 parts of two industries under NAICS 2017. Below are descriptions of the benefits, costs, and transfer impacts of increases to size standards.

Benefits of Increases to Size Standards

The benefits of adopting NAICS 2022 and the resulting increases to size standards will accrue to three groups in the following ways: (1) Some businesses that are currently above their current size standards may gain small business status, thereby becoming eligible to participate in Federal small business assistance programs, including SBA's 7(a) loan program, CDC/504 loan program, EIDL program, Surety Bond Guarantee Program, and Federal procurement and business development programs intended for small businesses; (2) Growing small businesses that are close to exceeding the current size standards for their NAICS 2017 industries may retain their small business status for a longer period under the new size standards under NAICS 2022, and can continue participating in the above programs; and (3) Federal Government agencies will have a larger pool of small businesses from which to draw to fulfill their small business procurement requirements because they

[4] The analysis of the disaster loan data excludes physical disaster loans that are available to anyone regardless of size, disaster loans issued to nonprofit entities, and EIDLs issued under the COVID–19 relief program. Effective January 1, 2022, SBA stopped accepting applications for new COVID EIDL loans or advances. Thus, the disaster loan analysis presented here pertains to the regular EIDL loans only. SBA estimates impacts of size standards changes on EIDL loans by calculating the ratio of businesses getting EIDL loans to total small businesses (based on the 2017 Economic Census data) and multiplying it by the number of impacted small firms. Due to data limitations, for FY 2019–20, some loans with both physical and EIDL loan components could not be broken into the physical and EIDL loan amounts. In such cases, SBA applied the ratio of EIDL amount to total (physical loan + EIDL) amount using FY 2016–18 data to the FY 2019–20 data to obtain the amount attributable to the EIDL loans.

will be able to define more accurately the principal purposes of their procurements under NAICS 2022 industry definitions.

The most significant benefit to businesses from increases to size standards is gaining or extending eligibility for Federal small business assistance programs. These include SBA's 7(a) loan program, CDC/504 loan program, EIDL program, Surety Bond Guarantee Program, and Federal procurement programs intended for small businesses. Federal procurement programs provide targeted, set-aside opportunities for small businesses. These include the 8(a) Business Development (BD) program, the Historically Underutilized Business Zones (HUBZone) program, the Women-Owned Small Businesses (WOSB) program, the Economically Disadvantaged Women-Owned Small Businesses (EDWOSB) program, and the Service-Disabled Veteran-Owned Small Businesses (SDVOSB) program.

For the affected NAICS 2017 industries or their parts for which size standards have increased, based on the 2017 Economic Census data, SBA estimates that approximately 450 additional businesses would gain small business status under the proposed size standards for 2022 NAICS industries. That represents about 0.6% of the total number of small businesses in the affected industries. SBA's size standards for new industries under NAICS 2022 would result in an increase to the small business share of total receipts in those 24 industries (*i.e.,* those with increases in size standards) from 40.7% to 45.7%. Table 10, Impacts of Increases to Size Standards for NAICS 2022 Industries, provides impacts of increasing size standards for 22 industries and 29 parts of two industries from NAICS 2017.

Table 10
Impacts of Increases to Size Standards for NAICS 2022 Industries

Impact Variable	Value
Number of industries with increases to size standards	24
Total current small businesses in industries with increases to size standards (2017 Economic Census)	80,454
Additional firms qualifying as small under standards (2017 Economic Census)	446
% of additional firms qualifying as small relative to current small businesses in industries with increases to size standards (2017 Economic Census)	0.6%
Number of current unique small firms getting small business contracts in industries with increases to size standards (FPDS-NG fiscal years 2018-2020)[1]	1,479
Additional small business firms getting small business status (FPDS-NG fiscal years 2018-2020)[1]	42
% increase to small businesses relative to current unique small firms getting small business contracts in industries with increases to size standards (FPDS-NG fiscal years 2018-2020)	2.8%
Total small business contract dollars under current standards in industries with increases to size standards ($ million) (FPDS-NG fiscal years 2018-2020)	$492.3
Estimated additional small business dollars available to newly- qualified small firms (using avg. dollars obligated to small businesses) ($ million) (FPDS-NG fiscal years 2018-2020)[2]	$60.4
% increase to small business dollars relative to total small business contract dollars under current standards in industries with increases to size standards	12.3%
Total number of 7(a) and 504 loans to small business in industries with increases to size standards (fiscal years 2018-2020)	887
Total 7(a) and 504 loan amounts to small businesses in industries with increases to size standards ($ million) (fiscal years 2018-2020)	$316.3
Estimated number of 7(a) and 504 loans to newly qualified small firms	1
Estimated 7(a) and 504 loan amounts to newly qualified small firms ($ million)	$0.01
% increase to 7(a) and 504 loan amount relative to the total amount of 7(a) and 504 loans in industries with increases to size standards	0.003%
Total number of EIDL loans to small businesses in industries with increases to size standards (fiscal years 2018-2020)[3]	92
Total amount of EIDL loans to small businesses in industries with increases to size standards ($ million) (fiscal years 2018-2020)[3]	$5.9
Estimated number of EIDL loans to newly qualified small firms[3]	0
Estimated EIDL loan amount to newly qualified small firms ($ million)[3]	$0.0
% increase to EIDL loan amount relative to the total amount of disaster loans in industries with increases to size standards[3]	0.0%

[1]Total impact represents total unique number of firms impacted to avoid double counting as some firms are participating in more than one industry.
[2]Additional dollars are calculated multiplying average small business dollars obligated per Data Universal Numbering System (DUNS) times change in number of firms. Numbers of firms are calculated using the SBA current size standard, not the contracting officer's size designation.
[3]Excludes COVID-19 related EIDL loans due to their temporary nature. Effective January 1, 2022, SBA stopped accepting applications for new COVID EIDL loans or advances.

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As shown in Table 10, based on the FPDS–NG data for fiscal years 2018–2020, SBA estimates that about 42 firms that are currently active in Federal contracting in those industries would gain small business status under the size standards for new industries under NAICS 2022. Based on the same data, SBA estimates that those newly-qualified small businesses under the size standards under NAICS 2022 could receive Federal small business contracts totaling about $60.4 million annually. That represents a 12.3% increase to Federal small business dollars from the baseline.

The added competition from more businesses qualifying as small can result in lower prices to certain Federal Government procurements set aside or reserved for small businesses, but SBA cannot quantify this impact precisely. Costs could also be higher when full and open contracts are awarded to HUBZone businesses that receive price evaluation preferences. However, with agencies likely setting aside more contracts for small businesses in response to the availability of a larger pool of small businesses under the new size standards, HUBZone firms might receive more set-aside contracts and fewer full and open contracts, thereby resulting in some cost savings to agencies. SBA cannot estimate such costs savings as it is impossible to determine the number and value of unrestricted contracts to be otherwise awarded to HUBZone firms will be awarded as set-aside contracts for small businesses. However, such cost savings are likely to be relatively small as only a small fraction of full and open contracts are awarded to HUBZone businesses.

Under SBA's 7(a) and CDC/504 loan programs, with more businesses qualifying as small under the new size standards under NAICS 2022, SBA will be able to guarantee more loans to small businesses. However, SBA expects the impact on loans to be minimal since applicants to SBA's financial assistance programs are typically much smaller than the industry size standard and most businesses that currently participate in the program would remain eligible for assistance even after this rule is adopted. Moreover, SBA does not anticipate that the increases to size standards will have a significant impact on the distribution of firms receiving loans by size of firm. Since SBA's size standards changes primarily impact firms at the higher margin of size standards, SBA estimates the impact to its financial assistance programs by estimating the number of loans and the amount of loans to firms greater than 10% below their size thresholds. SBA believes that expanding access to SBA's financial assistance programs will help all small businesses to adapt to changes in business environment, recover from disasters more quickly, and grow successfully, while having no impact on the ability of smaller small firms to access financial services from SBA.

Based on its internal data for fiscal years 2018–2020, SBA estimates that about one additional 7(a) and CDC/504 loans, totaling approximately $.01 million, could be made to the newly-defined small businesses under the proposed size standards under NAICS 2022. That represents a 0.003% increase to the loan amount compared to the baseline (see Table 10). The actual impact might be even smaller as the newly-qualified firms under the new size standards could have qualified anyway under the tangible net worth and net income based alternative size standard.

Newly-defined small businesses will also benefit from SBA's EIDL program, which, like SBA's 7(a) and CDC/504 loan program, typically provides loans to businesses that are much smaller than the industry size standard. Since this program is contingent on the occurrence and severity of a disaster, SBA cannot make a precise estimate of the future EIDL benefit. However, based on its internal disaster loan program data for fiscal years 2018–2020 and the amount of loans to firms greater than 10% below their size thresholds, SBA estimates that, on an annual basis, the newly-defined small businesses under the new size standards for NAICS 2022 would not be impacted.

Additionally, the newly-defined small businesses under proposed size standards under NAICS 2022 would also benefit through reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through the Federal Government programs, but SBA has no data to quantify this impact.

Costs of Increases to Size Standards

Aside from taking time to register in the System for Award Management (SAM) to be eligible to participate in Federal contracting and update the SAM profile annually, small businesses incur no direct costs to gain or retain their small business status under new size standards for NAICS 2022. All businesses willing to do business with the Federal Government must register in SAM and update their SAM profiles annually, regardless of their size status. SBA believes that a vast majority of businesses that are willing to participate in Federal contracting are already registered in SAM and update their SAM profiles annually. It is important to point out that most business entities that are already registered in SAM will not be required to update their SAM profiles. However, it will be incumbent on registrants to review, and update as necessary, their profiles to ensure that they have the correct NAICS codes. SAM requires that registered companies review and update their profiles annually, and therefore, businesses will need to pay particular attention to the changes to determine if they might affect them. They will also have to verify, and update, if necessary, their Representations and Certifications in SAM. More importantly, this final rule does not establish the new size standards for the very first time; rather it intends to modify the existing size standards to conform to new industry definitions under NAICS 2022.

To the extent that the newly-defined small firms under NAICS 2022 could become active in Federal procurement programs, this may entail some additional administrative costs to the Federal Government because of more businesses qualifying for Federal small business programs. For example, there will be more firms seeking SBA's loans, more firms eligible for enrollment in the SBA's Dynamic Small Business Search (DSBS) database or in *certify.sba.gov,* more firms seeking certifications as 8(a) BD or HUBZone firms, or qualifying for WOSB, EDWOSB, and SDVOSB status, and more firms applying for SBA's 8(a) BD mentor-protégé program.

Among those newly-defined small businesses seeking SBA's loans, there could be some additional costs associated with verification of their small business status. However, small business lenders have an option of using the tangible net worth and net income-based alternative size standard instead of using the industry-based size standards to establish eligibility for SBA's loans. For these reasons, SBA believes that these added administrative costs will be minor because necessary mechanisms are already in place to handle these added requirements.

Additionally, some Federal contracts may possibly have higher costs. With a greater number of businesses defined as small due to new size standards under NAICS 2022, Federal agencies may choose to set aside more contracts for competition among small businesses only instead of using a full and open competition. The movement of contracts from unrestricted competition to small business set-aside contracts might result in competition among fewer total bidders, although there will be more small businesses eligible to submit

offers under the new size standards. However, any additional costs associated with fewer bidders are expected to be minor since, by law, procurements may be set aside for small businesses under the 8(a)/BD, SDB, HUBZone, WOSB, EDWOSB, or SDVOSB programs only if awards are expected to be made at fair and reasonable prices.

Costs may also be higher when full and open contracts are awarded to HUBZone businesses that receive price evaluation preferences. However, with agencies likely setting aside more contracts for small businesses in response to the availability of a larger pool of small businesses under the adopted increases to size standards, HUBZone firms might receive fewer full and open contracts, thereby resulting in some cost savings to agencies. However, such cost savings are likely to be minimal as only a small fraction of unrestricted contracts are awarded to HUBZone businesses.

Transfer Impacts of Increases to Size Standards

The new size standards for the NAICS 2022 industries may result in some redistribution of Federal contracts between the newly-qualified small businesses and large businesses and between the newly-qualified small businesses and small businesses under the current size standards. However, it would have no impact on the overall economic activity since total Federal contract dollars available for businesses to compete for will not change with changes to size standards. While SBA cannot quantify with certainty the actual outcome of the gains and losses from the redistribution of contracts among different groups of businesses, it can identify several probable impacts in qualitative terms. With the availability of a larger pool of small businesses under the increases to size standards for 22 NAICS 2017 industries and 29 parts of two industries, some unrestricted Federal contracts that would otherwise be awarded to large businesses may be set aside for small businesses. As a result, large businesses may lose some Federal contracting opportunities. Similarly, some small businesses under the current size standards may obtain fewer set-aside contracts due to the increased competition from larger businesses qualifying as small under the new size standards for NAICS 2022 industries. This impact may be offset by a greater number of procurements being set aside for small businesses because of more businesses qualifying as small under the new size standards. With larger businesses qualifying as small under the higher size standards, smaller small businesses could face some disadvantage in competing for set-aside contracts against their larger counterparts. However, SBA cannot quantify these impacts.

Decreases to Size Standards

As stated above, SBA's size standards for the 111 new industries under NAICS 2022 have resulted in a decrease to the size standards for seven industries and 53 parts of two industries from NAICS 2017. Below are descriptions of the benefits, costs, and transfer impacts of these decreases to size standards.

Benefits of Decreases to Size Standards

The most significant benefit from decreases to size standards based on analytical results is to ensure that size standards are more reflective of latest industry structure and Federal market trends and that Federal small business assistance is more effectively targeted to its intended beneficiaries. These include SBA's 7(a) loan program, CDC/504 loan program, EIDL program, Surety Bond Guarantee Program, and Federal procurement programs. As stated previously, Federal procurement programs provide targeted, set-aside opportunities for small businesses under SBA's contracting and business development programs, such as small business, 8(a) BD, HUBZone, WOSB, EDWOSB, and SDVOSB programs. The adoption of size standards based on relevant data diminishes the risk of awarding Federal Government contracts or granting financial assistance to firms that are not small anymore. Lowering size standards would also reduce the risk of allowing the largest and potentially dominant firms to qualify as small and become eligible for Federal assistance intended for small businesses. This may provide a better chance for smaller small firms to grow and benefit from the opportunities available on the Federal marketplace and strengthen the small business industrial base for the Federal Government.

Costs of Decreases to Size Standards

Table 11, Impacts of Decreases to Size Standards, shows the various impacts of proposing to lower size standards in seven industries and 53 parts of two industries under NAICS 2017. Based on the 2017 Economic Census, about 849 (1.9%) firms would lose their small business status under the decreases to size standards.[5] However, many of these businesses were not found to have participated in Federal small businesses programs, including SBA's financial assistance and procurement programs, which suggests that impacts of above decreases to size standards would be fairly minimal. Similarly, based on the FPDS–NG data for fiscal years 2018–2020, SBA estimates that no small businesses participating in Federal contracting would lose their small status and become ineligible to compete for set-aside contracts. Thus, SBA believes these impacts are minimal.

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[5] Of the 849 firms losing small business status under the size standards for new industries under NAICS 2022 structure, 808 (or 95.1%) belong to NAICS 2017 industry 454110 (Electronic Shopping and Mail-Order Houses). NAICS 454110, with a $41.5 million size standard, was split and distributed among 42 other Retail Trade industries, resulting in a decrease to the size standard for 40 parts and no change to the size standard for one part. This would have very minimal impact on firms seeking SBA's financial assistance as firms receiving such assistance are typically much smaller than the size standard. Moreover, businesses not qualifying as small for financial assistance under the industry size standard, could still qualify under the tangible net worth and net income based alternative size standard. The reduction in size standard for NAICS 454110 would have no impact on small businesses seeking Federal contracts as that NAICS code does not apply to Federal contracting.

Table 11
Impacts of Decreases to Size Standards

Impact Variable	Value
Number of industries for which SBA decreases size standards	9
Total current small businesses in industries for which SBA decreases size standards (2017 Economic Census)	45,395
Estimated number of firms losing small status in industries for which SBA decreases size standards (2017 Economic Census)	849
% of firms losing small status relative to current small businesses in industries for which SBA decreases size standards (2017 Economic Census)	1.9%
Number of current unique small firms getting small business contracts in industries for which SBA decreases size standards (FPDS-NG FY 2018-2020) [1]	30
Estimated number of small business firms that would have lost small business status in industries for which SBA decreases size standards (FPDS-NG FY 2018-2020)[1]	0
% decrease to small business firms relative to current unique small firms getting small business contracts in industries for which SBA decreases size standards (FPDS-NG FY 2018-2020)[1]	0%

Total small business contract dollars under current size standards in industries for which SBA decreases size standards ($ million) (FPDS-NG FY 2018-2020)	$3.3
Estimated small business dollars not available to firms losing small business status in industries for which SBA decreases size standards ($ million) (FPDS-NG FY 2018-2020)[2]	0
% decrease to small business dollars relative to total small business contract dollars under current size standards in industries for which SBA decreases size standards	0%
Total number of 7(a) and 504 loans to small businesses in industries for which SBA decreases size standards (FY 2018-2020)	450
Total amount of 7(a) and 504 loans to small businesses in industries for which SBA decreases size standards ($ million) (FY 2018-2020)	$160.7
Estimated number of 7(a) and 504 loans not available to firms that would have lost small business status in industries for which SBA decreases size standards	1
Estimated 7(a) and 504 loan amount not available to firms that would have lost small status ($ million)	$0.001
% decrease to 7(a) and 504 loan amount relative to the total amount of 7(a) and 504 loans in industries for which SBA decreases size standards	0.0%
Total number of EIDL loans to small businesses in industries for which SBA decreases size standards (FY 2018-2020)[3]	13
Total amount of EIDL loans to small businesses in industries for which SBA decreases size standards ($ million) (FY 2018-2020)[3]	$0.6
Estimated number of EIDL loans not available to firms that would have lost small business status in industries for which SBA decreases size standards[3]	0
Estimated EIDL loan amount not available to firms that would have lost small business status ($ million)[3]	$0.0
% decrease to EIDL loan amount relative to the baseline[3]	0.0%

[1]Total impact represents total unique number of firms impacted to avoid double counting as some firms participate in more than one industry.
[2]Additional dollars are calculated multiplying average small business dollars obligated per unique small firm times change in number of firms. Numbers of firms are calculated using the SBA's current size standards, not the contracting officer's size designation.
[3]Excludes COVID-19 related EIDL loans due to their temporary nature. Effective January 1, 2022, SBA stopped accepting applications for new COVID EIDL loans or advances.

Transfer Impacts of Decreases to Size Standards

If the size standards are decreased, it may result in a redistribution of Federal contracts between small businesses losing their small business status and large businesses; and between small businesses losing their small business status and small businesses remaining small under the reduced size standards. However, as under the increases to size standards, this would have no impact on the overall economic activity since the total Federal contract dollars available for businesses to compete for will stay the same. While SBA cannot estimate with certainty the actual outcome of the gains and losses among different groups of businesses from contract redistribution resulting from decreases to size standards, it can identify several probable impacts. With a smaller pool of small businesses under the decreases to size standards, some set-aside Federal contracts to be otherwise awarded to small businesses may be competed on an unrestricted

basis. As a result, large businesses may have more Federal contracting opportunities. However, because agencies are still required by law to award 23% of Federal dollars to small businesses, SBA expects the movement of set-aside contracts to unrestricted competition to be limited. For the same reason, small businesses under the reduced size standards are likely to obtain more set-aside contracts due to the reduced competition from fewer businesses qualifying as small under the decreases to size standards. With some larger small businesses losing small business status under the decreases to size standards, smaller small businesses would likely become more competitive in obtaining set-aside contracts. However, SBA cannot quantify these impacts.

Net Impacts of Size Standards Changes

The impacts of the increases of size standards for 22 industries and 29 parts of two industries were shown in Table 10 (above). Similarly, the impacts of decreases of size standards for seven industries and 53 parts of two industries were presented in Table 11 (above). Table 12, Net Impacts of Size Standards Changes, below, presents the net impacts of changes to size standards for 29 industries and 82 parts of four industries.

Based on the 2017 Economic Census, SBA estimates that when moving from NAICS 2017 to NAICS 2022, 29 industries and 82 parts of four industries resulted in size standard changes. About 403 firms (almost all in NAICS 2017 industry 454110) would not qualify as small under the new size standards for NAICS 2022 industries. That represents about 0.3% of all firms classified as small in those industries and industry parts under the current size standards.

Table 12
Net Impacts of Size Standards Changes

Impact Variable	Value
Number of industries or industry parts with changes to size standards	33
Total number of small firms under the current size standards in industries with changes to size standards (2017 Economic Census)	125,850
Additional number of firms qualifying as small under size standards changes (2017 Economic Census)	-403
% of additional firms qualifying as small relative to total current small firms (2017 Economic Census)	-0.3%
Number of current unique small firms getting small business contracts in industries with changes to size standards (FPDS-NG FY 2018-2020)[1]	1,509
Additional number of unique small firms gaining small business status in industries with changes to size standards (FPDS-NG FY 2018-2020)[1]	42
% increase to small firms relative to current unique small firms gaining small business status (FPDS-NG FY 2018-2020)	2.8%

Total small business contract dollars under current size standards in industries with changes to size standards ($ million) (FPDS-NG FY 2018-2020)	$495.6
Estimated small business dollars available to newly qualified small firms ($ million) (FPDS-NG FY 2018-2020)[2]	$60.4
% increase to dollars relative to total small business contract dollars under current size standards	12.2%
Total number of 7(a) and 504 loans to small businesses in industries with changes to size standards (FY 2018-2020)	1,337
Additional number of 7(a) and 504 loans to small businesses in industries with changes to size standards (FY 2018-2020)	0
% of additional 7(a) and 504 loans to small businesses in industries with changes to size standards	0.0%
Total amount of 7(a) and 504 loans to small businesses in industries with changes to size standards ($ million) (FY 2018-2020)	$477.0
Estimated additional 7(a) and 504 loan amount to newly-qualified small firms ($ million)	$0.0
% increase to 7(a)and 504 loan amount relative to the total amount of 7(a) and 504 loans to small businesses	0.0%
Total number of EIDL loans to small businesses in industries with changes to size standards (FY 2018-2020)[3]	105
Estimated number of additional EIDL loans to newly-qualified small firms (FY 2018-2020)[3]	0
% of additional EIDL loans to small businesses in industries with changes to size standards	0.0%
Total amount of EIDL loans to small businesses in industries with changes to size standards ($ million) (FY 2018-2020)[3]	$6.5
Estimated additional EIDL loan amount to newly-qualified small firms ($ million)[3] (FY2018-2020)	$0.0
% increase to EIDL loan amount relative to the total amount of disaster loans to small businesses[3]	0.0%

[1]Total impact represents total unique number of firms impacted to avoid double counting as some firms participate in more than one industry.

[2]Additional dollars are calculated multiplying average small business dollars obligated per unique firm times change in number of firms. Numbers of firms are calculated using the SBA's current size standards, not the contracting officer's size designation.

[3]Excludes COVID-19 related EIDL loans due to their temporary nature. Effective January 1, 2022, SBA stopped accepting applications for new COVID EIDL loans or advances.

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Based on the FPDS–NG data for fiscal years 2018–2020, SBA estimates that about 42 unique active firms in Federal contracting in those industries would gain their small business status under the changes to size standards, most of them in Sector 31–33 (Manufacturing). This represents an increase of about 2.8% of the total number of small businesses participating in Federal contracting under the current size standards. Based on the same data, SBA estimates that about $60.4 million of Federal procurement dollars would become available to all small firms,

including those gaining small status. This represents an increase of 12.2% from the baseline. SBA estimates that the dollars obligated to small businesses will increase despite a reduction in the total number of small firms because the contract dollars to newly-qualified small businesses in sectors with increases to size standards is higher than the contract dollars to small businesses losing small business status in sectors with decreases to size standards.

Based on the SBA's loan data for fiscal years 2018–2020, the total number of 7(a) and CDC/504 loans will not be impacted, and the loan amount may increase slightly since the average loan value to firms with increases to size standards is higher than the average loan value to firms with decreases to size standards.

Firms' participation under the SBA's EIDL program will be affected as well. Since the benefit provided through this program is contingent on the occurrence and severity of a disaster in the future, SBA cannot make a meaningful estimate of this impact. However, based on the disaster loan program data for fiscal years 2018–2020, SBA estimates that the total number of EIDL loans and the loan amount will not be impacted.

3. What alternatives have been considered?

As stated previously, as an alternative to adopting new size standards for NAICS 2022 industries, SBA considered retaining NAICS 2017 as the basis of industry definitions for its small business size standards. That would, however, lead to inconsistencies between SBA's size standards and establishment data published by Federal agencies that will adopt NAICS 2022 for their statistical and other data collection programs. OMB stated in its December 21, 2021, notice that ''Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using the 2022 NAICS United States codes.'' SBA is not a statistical agency, but it uses for its size standards analyses establishment data collected by other Federal agencies, such as the Economic Census data and County Business Patterns from the U.S. Census Bureau. If SBA continues using NAICS 2017 for its size standards, it will not be able to analyze and evaluate industry structure adequately and accurately and adjust small business size standards appropriately because the forthcoming Economic Census and County Business Patterns data based on NAICS 2022 will not be compatible with NAICS 2017 industry definitions. That would run counter to the Jobs Act mandate that requires SBA to review all size standards and adjust them appropriately to reflect the current industry structure and market conditions every five years.

To establish, review, or revise, where necessary, small business size standards, SBA uses special tabulations of industry data that it obtains from the U.S. Census Bureau based on its Economic Census of U.S. industries and businesses, and establishment data from its County Business Patterns (CBP). Because the 2022 Economic Census and CBP data will be based on NAICS 2022 industry definitions, it is imperative that SBA also use NAICS 2022 as the basis of industry definitions for its table of small business size standards.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (codified at 5 U.S.C. 801–808), also known as the Congressional Review Act or CRA, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. SBA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the CRA cannot take effect until 60 days after it is published in the **Federal Register**. OMB's Office of Information and Regulatory Affairs has determined that this rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Final Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act (RFA), this final rule may have a significant impact on a substantial number of small businesses in some industries whose size standards have been changed as a result of adopting NAICS 2022 for size standards. As described above, this rule may affect small businesses applying for Federal Government contracts, loans under SBA's 7(a), 504, and EIDL Programs, and assistance under other Federal small business programs.

Immediately below, SBA sets forth a final regulatory flexibility analysis (FRFA) of this final rule addressing the following questions: (1) What are the need for and objectives of the rule?; (2) What are SBA's description and estimate of the number of small businesses to which the rule will apply?; (3) What are the projected reporting, record keeping, and other compliance requirements of the rule?; (4) What are the relevant Federal rules that may duplicate, overlap, or conflict with the rule?; and (5) What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small businesses?

1. What are the need for and objective of the rule?

The Small Business Act requires that small business size standards vary from industry to industry reflecting the differing characteristics of the various industries. SBA uses the latest NAICS as a basis of industries definitions for its table of size standards. As part of its five-year review of and revisions to NAICS industry definitions, OMB published its latest NAICS revision, NAICS 2022, on December 21, 2021. According to the OMB's notice, Federal establishment and industry data for reference years beginning on or after January 1, 2022, should be published using NAICS 2022. This rule amends SBA's small business size regulations to incorporate NAICS 2022 into its table of size standards. This not only makes SBA's size standards more reflective of the latest industry differences but also makes them more consistent with latest industry data the Agency uses to establish, review or adjust size standards. Updating size standards to the latest industry definitions also serves the SBA's mandate to review all size standards and make appropriate adjustments to reflect market conditions under the Jobs Act.

2. What are SBA's description and estimate of the number of small businesses to which the rule will apply?

With the update of size standards to the latest industry definitions under NAICS 2022, Federal small business assistance is more effectively targeted to its intended beneficiaries. The NAICS 2022 revision created 111 new industries by reclassifying, combining, or splitting 156 NAICS 2017 industries or their parts. SBA's size standards for these 111 new industries under NAICS 2022 will result in an increase to the size standards for 22 industries and 29 parts of two industries under NAICS 2017, a decrease to size standards for seven industries and 53 parts of two industries, a change in the size standard measure from average annual receipts to number of employees for one industry, a change in the size standard measure from number of employees to average annual receipts for a part of one industry, and no change in size standards for 117 industries and 19 parts of seven industries. In 22 industries and 29 parts of two industries whose size standards would increase due to the adoption of NAICS 2022, nearly 450 firms above the current size standards would qualify as small under the updated size standards, thereby

making them eligible for Federal small business assistance programs. Based on the data for fiscal years 2018–2020, SBA estimates that approximately $60.0 million in Federal contracts and about $100,000 in SBA 7(a) and 504 loans could be awarded to the newly defined small businesses under the updated size standards. The updated size standards would enable advanced small businesses to maintain their small business size status for a longer period and some mid-size businesses (*i.e.,* businesses that have just exceeded the size thresholds) regain their small business status. In the seven NAICS 2017 industries and 53 parts of two industries for which size standards will decrease as a result of adoption of NAICS 2022, 849 firms below the current size standards would lose their small business size status under the proposed size standards. However, the program data suggests that this would cause no impact on them in terms of access to Federal contracting and SBA's loans programs. Currently, they are not participating in any small business programs.

3. What are the projected reporting, record keeping and other compliance requirements of the rule?

The size standard changes due to the adoption of NAICS 2022 impose no additional reporting or record keeping requirements on small businesses. However, qualifying for Federal small business contracting and other programs may require businesses to register in SAM and recertify in SAM that they are small at least once annually. Therefore, the newly qualified small businesses opting to participate in those programs must comply with SAM requirements. There are minimal costs associated with SAM registration and annual recertification, but this final rule does not impose any new costs in this area. Changing size standards alters the access to SBA's financial and other Federal programs that assist small businesses but does not impose a regulatory burden because they neither regulate nor control business behavior.

4. What are the relevant Federal rules, which may duplicate, overlap, or conflict with the rule?

Under section 3(a)(2)(C) of the Small Business Act, 15 U.S.C. 632(a)(2)(c), Federal agencies must generally use SBA's size standards to define a small business, unless specifically authorized by statute to do otherwise. In 1995, SBA published in the **Federal Register** a list of statutory and regulatory size standards that identified the application of SBA's size standards as well as other size standards used by Federal agencies (60 FR 57988 (November 24, 1995)). An agency may establish for its programs a size standard that is different from those established by SBA if approved by SBA's Administrator in accordance with 13 CFR 121.903. SBA is not aware of any Federal rule that would duplicate or conflict with establishing or updating size standards.

However, the Small Business Act and SBA's regulations allow Federal agencies to develop different size standards if they believe that SBA's size standards are not appropriate for their programs, with the approval of SBA's Administrator (13 CFR 121.903). The RFA authorizes a Federal agency to establish an alternative small business definition, after consultation with the Office of Advocacy of the U.S. Small Business Administration (5 U.S.C. 601(3)).

5. What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

By law, SBA is required to develop numerical size standards for establishing eligibility for Federal small business assistance programs. Other than varying levels of size standards by industry and changing the size measures, no practical alternative exists to the systems of numerical size standards. As stated previously, SBA considered continuing to use NAICS 2017 as a basis of industry definitions for its table of size standards. However, that would render SBA's table of size standards incompatible with Federal industry and establishment statistics and other databases when evaluating industry characteristics to ensure size standards are reflective of current industry structure and market conditions.

Executive Order 13563

A description of the need for this proposed regulatory action and benefits and costs associated with this action including possible distribution impacts that relate to Executive Order 13563 are included above in the Cost Benefit Analysis.

To engage interested parties in this action, SBA reached out to all Federal agencies advising them that the Agency plans to update its table of size standards to NAICS 2022, effective October 1, 2022, and that agencies must continue using the current size standards until that date. Adopting the updated size standards on October 1, 2022, is consistent with SBA's adoptions of previous NAICS revisions at the beginning of the new fiscal year following the OMB's January 1 effective date of NAICS revisions for Federal statistical agencies.

Unlike the most previous NAICS revisions which SBA adopted for its size standards either through a direct final rule or through an interim final rule, for the adoption of NAICS 2022 revision, SBA issued this proposed rule and sought comments to better engage the public in the process. SBA received two comments during the comment period which SBA has summarized and discussed above in the Discussion of Comments section. SBA also updated the size standards web page at *www.sba.gov/size,* asking interested parties to comment on the rule. SBA thoroughly considered all public comments when developing this final rule.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

For purposes of Executive Order 13132, SBA has determined that this final rule will not have substantial, direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, SBA has determined that this final rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act

For the purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this final rule would not impose any new reporting or record keeping requirements.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Federal Government procurement, Federal Government property, Grant programs—Business, Individuals with disabilities, Loan programs—Business, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, SBA amends 13 CFR part 121 as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 is revised to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(a)(36), 662, 694a(9), and 9012.

■ 2. In § 121.201, amend the table, ''Small Business Size Standards by NAICS Industry'' as follows:
■ a. Remove the entries for 212111, 212112, and 212113;
■ b. Add entries for 212114, 212115, and 212220 in numerical order;
■ c. Remove the entries for 212221 and 212222;
■ d. Add an entry for 212290 in numerical order;
■ e. Remove the entries for 212291 and 212299;
■ f. Add an entry for 212323 in numerical order;
■ g. Remove the entries for 212324 and 212325;
■ h. Add an entry for 212390 in numerical order;
■ i. Remove the entries for 212391, 212392, 212393, and 212399;
■ j. Revise entry 311221;
■ k. Remove the entry for 315110;
■ l. Add an entry for 315120 in numerical order;
■ m. Remove the entries for 315190, 315220, and 315240;
■ n. Add an entry for 315250 in numerical order;
■ o. Remove the entry for 315280;
■ p. Add an entry for 316990 in numerical order;
■ q. Remove the entries for 316992, 316998, 321213, and 321214;
■ r. Add entries for 321215 and 322120 in numerical order;
■ s. Remove the entries for 322121 and 322122;
■ t. Add an entry for 325315 in numerical order;
■ u. Revise entry 325992;
■ v. Remove the entry for 333244;
■ w. Add an entry for 333248 in numerical order;
■ x. Remove the entry for 333249;
■ y. Add an entry for 333310 in numerical order;
■ z. Remove the entries for 333314, 333316, 333318, and 333997;
■ aa. Add an entry for 333998 in numerical order;
■ bb. Remove the entry for 333999;
■ cc. Add an entry for 334610 in numerical order;
■ dd. Remove the entries for 334613, 334614, 335110, 335121, 335122, and 335129.
■ ee. Add entries for 335131, 335132, 335139, and 335910 in numerical order;
■ ff. Remove the entries for 335911 and 335912;
■ gg. Add an entry for 336110 in numerical order;
■ hh. Remove the entries for 336111, 336112, 337124, and 337125;
■ ii. Add an entry for 337126 in numerical order;
■ jj. Remove the entries for 424320 and 424330;
■ kk. Add an entry for 424350 in numerical order;
■ ll. Revise entry 424940 and the heading for Subsector 425;
■ mm. Remove the entry for 425110;
■ nn. Add an entry for 441227 in numerical order;
■ oo. Remove the entries for 441228, 441310, and 441320;
■ pp. Add entries for 441330 and 441340 in numerical order;
■ qq. Remove Subsectors 442 and 443;
■ rr. Revise entry 444120;
■ ss. Remove the entry for 444130;
■ tt. Add entries for 444140 and 444180 in numerical order;
■ uu. Remove the entries for 444190, 444210, and 444220;
■ vv. Add entries for 444230 and 444240 in numerical order;
■ ww. Revise Subsector 445;
■ xx. Remove Subsectors 446, 447, and 448;
■ yy. Add Subsector 449 in numerical order;
■ zz. Remove Subsectors 451, 452, 453, and 454;
■ aaa. Add Subsectors 455, 456, 457, 458, and 459 in numerical order;
■ bbb. Revise entry 485310;
■ ccc. Remove Subsector 511;
■ ddd. Add Subsector 513 in numerical order;
■ eee. Remove Subsector 515;
■ fff. Add Subsector 516 in numerical order;
■ ggg. Revise Subsectors 517, 518, and 519;
■ hhh. Remove the entry for 522120;
■ iii. Add an entry for 522180 in numerical order;
■ jjj. Remove the entries for 522190, 522293, 522294, and 522298;
■ kkk. Add an entry for 522299 in numerical order;
■ lll. Remove the entries for 523110, 523120, 523130, and 523140;
■ mmm. Add entries for 523150 and 523160 in numerical order;
■ nnn. Remove the entries for 523920 and 523930;
■ ooo. Add an entry for 523940 in numerical order;
■ ppp. Revise entries for 524292, 541380, 541850, 561611, and 624410;
■ qqq. Remove the entries for 811112 and 811113;
■ rrr. Add an entry for 811114 in numerical order;
■ sss. Remove the entry for 811118;
■ ttt. Add an entry for 811210 in numerical order;
■ uuu. Remove the entries for 811211, 811212, 811213, and 811219; and
■ vvv. Revise footnotes 8 and 15 at the end of the table.

The additions and revisions read as follows:

§ 121.201 What size standards has SBA identified by North American U.S. Industry Classification System codes?

* * * * *

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
Sector 21—Mining, Quarrying, and Oil and Gas Extraction			
*	* * * * *	*	*
Subsector 212—Mining (except Oil and Gas)			
212114	Surface Coal Mining		1,250
212115	Underground Coal Mining		1,500
*	* * * * *	*	*
212220	Gold Ore and Silver Ore Mining		1,500

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
212290	Other Metal Ore Mining		750
*	* * * * *	*	*
212323	Kaolin, Clay, and Ceramic and Refractory Minerals Mining		500
212390	Other Nonmetallic Mineral Mining and Quarrying		500
*	* * * * *	*	*
	Sectors 31–33—Manufacturing		
	Subsector 311—Food Manufacturing		
*	* * * * *	*	*
311221	Wet Corn Milling and Starch Manufacturing		1,250
*	* * * * *	*	*
	Subsector 315—Apparel Manufacturing		
315120	Apparel Knitting Mills		750
*	* * * * *	*	*
315250	Cut and Sew Apparel Manufacturing (except Contractors)		750
*	* * * * *	*	*
	Subsector 316—Leather and Allied Product Manufacturing		
*	* * * * *	*	*
316990	Other Leather and Allied Product Manufacturing		500
	Subsector 321—Wood Product Manufacturing		
*	* * * * *	*	*
321215	Engineered Wood Member Manufacturing		500
*	* * * * *	*	*
	Subsector 322—Paper Manufacturing		
*	* * * * *	*	*
322120	Paper Mills		1,250
*	* * * * *	*	*
	Subsector 325—Chemical Manufacturing		
*	* * * * *	*	*
325315	Compost Manufacturing		500
*	* * * * *	*	*
325992	Photographic Film, Paper, Plate, Chemical, and Copy Toner Manufacturing		1,500
*	* * * * *	*	*
	Subsector 333—Machinery Manufacturing [6]		
*	* * * * *	*	*
333248	All Other Industrial Machinery Manufacturing		750
333310	Commercial and Service Industry Machinery Manufacturing		1,000

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
333998	All Other Miscellaneous General Purpose Machinery Manufacturing		500
	Subsector 334—Computer and Electronic Product Manufacturing [6]		
*	* * * * *	*	*
334610	Manufacturing and Reproducing Magnetic and Optical Media		1,250
	Subsector 335—Electrical Equipment, Appliance and Component Manufacturing [6]		
335131	Residential Electric Lighting Fixture Manufacturing		750
335132	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing		500
335139	Electric Lamp Bulb and Other Lighting Equipment Manufacturing		1,250
*	* * * * *	*	*
335910	Battery Manufacturing		1,250
*	* * * * *	*	*
	Subsector 336—Transportation Equipment Manufacturing [6]		
336110	Automobile and Light Duty Motor Vehicle Manufacturing		1,500
*	* * * * *	*	*
	Subsector 337—Furniture and Related Product Manufacturing		
*	* * * * *	*	*
337126	Household Furniture (except Wood and Upholstered) Manufacturing		750
*	* * * * *	*	*
	Sector 42—Wholesale Trade		
*	* * * * *	*	*
	Subsector 424—Merchant Wholesalers, Nondurable Goods		
*	* * * * *	*	*
424350	Clothing and Clothing Accessories Merchant Wholesalers		150
*	* * * * *	*	*
424940	Tobacco Product and Electronic Cigarette Merchant Wholesalers		250
*	* * * * *	*	*
	Subsector 425—Wholesale Trade Agents and Brokers		
*	* * * * *	*	*
	Sector 44–45—Retail Trade		
*	* * * * *	*	*
	Subsector 441—Motor Vehicles and Parts Dealers		
*	* * * * *	*	*
441227	Motorcycle, ATV, and All Other Motor Vehicle Dealers	$35.0	
441330	Automotive Parts and Accessories Retailers	25.0	
441340	Tire Dealers	22.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
Subsector 444—Building Material and Garden Equipment and Supplies Dealers			
*	* * * * * *	*	*
444120	Paint and Wallpaper Retailers	30.0	
444140	Hardware Retailers	14.5	
444180	Other Building Material Dealers	22.0	
444230	Outdoor Power Equipment Retailers	8.5	
444240	Nursery, Garden Center, and Farm Supply Retailers	19.0	
Subsector 445—Food and Beverage Retailers			
445110	Supermarkets and Other Grocery Retailers (except Convenience Retailers)	35.0	
445131	Convenience Retailers	32.0	
445132	Vending Machine Operators	18.5	
445230	Fruit and Vegetable Retailers	8.0	
445240	Meat Retailers	8.0	
445250	Fish and Seafood Retailers	8.0	
445291	Baked Goods Retailers	14.0	
445292	Confectionery and Nut Retailers	17.0	
445298	All Other Specialty Food Retailers	9.0	
445320	Beer, Wine, and Liquor Retailers	9.0	
Subsector 449—Furniture, Home Furnishings, Electronics, and Appliance Retailers			
449110	Furniture Retailers	22.0	
449121	Floor Covering Retailers	8.0	
449122	Window Treatment Retailers	10.0	
449129	All Other Home Furnishings Retailers	29.5	
449210	Electronics and Appliance Retailers	35.0	
Subsector 455—General Merchandise Retailers			
455110	Department Stores	35.0	
455211	Warehouse Clubs and Supercenters	41.5	
455219	All Other General Merchandise Retailers	35.0	
Subsector 456—Health and Personal Care Retailers			
456110	Pharmacies and Drug Retailers	33.0	
456120	Cosmetics, Beauty Supplies, and Perfume Retailers	30.0	
456130	Optical Goods Retailers	26.0	
456191	Food (Health) Supplement Retailers	20.0	
456199	All Other Health and Personal Care Retailers	8.5	
Subsector 457—Gasoline Stations and Fuel Dealers			
457110	Gasoline Stations with Convenience Stores	32.0	
457120	Other Gasoline Stations	29.5	
457210	Fuel Dealers		100
Subsector 458—Clothing, Clothing Accessories, Shoe, and Jewelry Retailers			
458110	Clothing and Clothing Accessories Retailers	41.5	
458210	Shoe Retailers	30.0	
458310	Jewelry Retailers	18.0	
458320	Luggage and Leather Goods Retailers	33.5	
Subsector 459—Sporting Goods, Hobby, Musical Instrument, Book, and Miscellaneous Retailers			
459110	Sporting Goods Retailers	23.5	
459120	Hobby, Toy, and Game Retailers	31.0	
459130	Sewing, Needlework, and Piece Goods Retailers	30.0	
459140	Musical Instrument and Supplies Retailers	20.0	
459210	Book Retailers and News Dealers	31.5	
459310	Florists	8.0	
459410	Office Supplies and Stationery Retailers	35.0	
459420	Gift, Novelty, and Souvenir Retailers	12.0	
459510	Used Merchandise Retailers	12.5	
459910	Pet and Pet Supplies Retailers	28.0	
459920	Art Dealers	14.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
459930	Manufactured (Mobile) Home Dealers	16.5	
459991	Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers	10.0	
459999	All Other Miscellaneous Retailers	10.0	
Sectors 48–49—Transportation and Warehousing			
*	* * * * *	*	*
Subsector 485—Transit and Ground Passenger Transportation			
*	* * * * *	*	*
485310	Taxi and Ridesharing Services	16.5	
*	* * * * *	*	*
Sector 51—Information			
*	* * * * *	*	*
Subsector 513—Publishing Industries			
513110	Newspaper Publishers		1,000
513120	Periodical Publishers		1,000
513130	Book Publishers		1,000
513140	Directory and Mailing List Publishers		1,000
513191	Greeting Card Publishers		1,000
513199	All Other Publishers		1,000
513210	Software Publishers [15]	[15] 41.5	
Subsector 516—Broadcasting and Content Providers			
516110	Radio Broadcasting Stations	41.5	
516120	Television Broadcasting Stations	41.5	
516210	Media Streaming Distribution Services, Social Networks, and Other Media Networks and Content Providers.	41.5	
Subsector 517—Telecommunications			
517111	Wired Telecommunications Carriers		1,500
517112	Wireless Telecommunications Carriers (except Satellite)		1,500
517121	Telecommunications Resellers		1,500
517122	Agents for Wireless Telecommunications Services		1,500
517410	Satellite Communications	38.5	
517810	All Other Telecommunications	35.0	
Subsector 518—Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services			
518210	Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services.	35.0	
Subsector 519—Web Search Portals, Libraries, Archives, and Other Information Services			
519210	Libraries and Archives	18.5	
519290	Web Search Portals and All Other Information Services		1,000
Sector 52—Finance and Insurance			
Subsector 522—Credit Intermediation and Related Activities			
*	* * * * *	*	*
522180	Savings Institutions and Other Depository Credit Intermediation [8]	750.0 million in average assets [8]	
*	* * * * *	*	*
522299	International, Secondary Market, and All Other Nondepository Credit Intermediation	41.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
	Subsector 523—Securities, Commodity Contracts, and Other Financial Investments and Related Activities		
523150	Investment Banking and Securities Intermediation	41.5	
523160	Commodity Contracts Intermediation	41.5	
*	* * * * *	*	*
523940	Portfolio Management and Investment Advice	41.5	
*	* * * * *	*	*
	Subsector 524—Insurance Carriers and Related Activities		
*	* * * * *	*	*
524292	Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds.	40.0	
*	* * * * *	*	*
	Sector 54—Professional, Scientific and Technical Services		
	Subsector 541—Professional, Scientific and Technical Services		
*	* * * * *	*	*
541380	Testing Laboratories and Services	16.5	
*	* * * * *	*	*
541850	Indoor and Outdoor Display Advertising	30.5	
*	* * * * *	*	*
	Sector 56—Administrative and Support and Waste Management and Remediation Services		
	Subsector 561—Administrative and Support Services		
*	* * * * *	*	*
561611	Investigation and Personal Background Check Services	22.0	
*	* * * * *	*	*
	Sector 62—Health Care and Social Assistance		
*	* * * * *	*	*
	Subsector 624—Social Assistance		
*	* * * * *	*	*
624410	Child Care Services	8.5	
*	* * * * *	*	*
	Sector 81—Other Services (Except Public Administration)		
	Subsector 811—Repair and Maintenance		
*	* * * * *	*	*
811114	Specialized Automotive Repair	8.0	
*	* * * * *	*	*
811210	Electronic and Precision Equipment Repair and Maintenance	30.0	
*	* * * * *	*	*
Footnotes			
*	* * * * *	*	*

6. *NAICS Subsectors 333, 334, 335 and 336*—For rebuilding machinery or equipment on a factory basis, or equivalent, use the NAICS code for a newly manufactured product. Concerns performing major rebuilding or overhaul activities do not necessarily have to meet the criteria for being a ''manufacturer'' although the activities may be classified under a manufacturing NAICS code. Ordinary repair services or preservation are not considered rebuilding.

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8. *NAICS Codes 522110, 522130, 522180, and 522210*—A financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year. ''Assets'' for the purposes of this size standard means the assets defined according to the Federal Financial Institutions Examination Council 041 call report form for NAICS codes 522110, 522180, and 522210 and the National Credit Union Administration 5300 call report form for NAICS code 522130.

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15. *NAICS code 513210*—For purposes of Government procurement, the purchase of software subject to potential waiver of the nonmanufacturer rule pursuant to § 121.1203(d) should be classified under this NAICS code.

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Isabella Casillas Guzman,

Administrator.

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